

Michael P. Matthews (*pro hac vice*)  
FOLEY & LARDNER LLP  
100 N. Tampa Street, Suite 2700  
Tampa, Florida 33602-5810  
(813) 225-4131  
mmatthews@foley.com

Lawrence M. Kraus (*pro hac vice*)  
FOLEY & LARDNER LLP  
111 Huntington Avenue, Suite 2500  
Boston, MA 02199-7610  
(617) 342-4070  
lkraus@foley.com

Rachel E. Kramer  
FOLEY & LARDNER LLP  
90 Park Avenue  
New York, New York 10016  
(212) 338-3545  
rkramer@foley.com

*Attorneys for Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A.*

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel.  
DON HANKS, et al.

Plaintiffs,

-against-

U.S. ONCOLOGY SPECIALTY, LLP et al.,

Defendants.

No. 08-cv-3096-SJ-RML

**NOTICE OF MOTION  
TO DISMISS**

Hon. Sterling Johnson, Jr.

TO: All Counsel of Record

PLEASE TAKE NOTICE that, for the reasons stated in the Memorandum of Law submitted herewith and upon the accompanying Declaration of Rachel Kramer, Defendants Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute), Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center, Coastal Oncology, P.L., J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates), and Pasco Hernando Oncology Associates, P.A. will apply to this Court, before the Honorable Sterling Johnson, Jr., United States District Judge, at the United States Courthouse, 225 Cadman Plaza East, Brooklyn, New York 11201, on September 19, 2014 at 9:30 a.m., for an order dismissing the Fifth Amended Complaint in this action pursuant to Federal Rules of Civil Procedure 12(b)(6), 9(b), and 12(b)(1), among other grounds.

Dated: New York, New York  
August 1, 2014

FOLEY & LARDNER LLP

By: s/Lawrence M. Kraus  
Lawrence M. Kraus (*pro hac vice*)  
111 Huntington Avenue, Suite 2500  
Boston, MA 02199-7610  
(617) 342-4070  
lkraus@foley.com

Michael P. Matthews (*pro hac vice*)  
FOLEY & LARDNER LLP  
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Rachel E. Kramer  
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New York, New York 10016  
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rkramer@foley.com

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Hon. Sterling Johnson, Jr.

**MEMORANDUM OF LAW IN SUPPORT OF MOTION BY DEFENDANTS  
FLORIDA CANCER SPECIALISTS, P.L., AYUB, SOKOL, MATZKOWITZ AND  
SENNABAUM, M.D.S, P.A. D/B/A NEW HOPE CANCER CENTER, COASTAL  
ONCOLOGY, P.L., J. PAONESSA, M.D., P.A., AND PASCO HERNANDO ONCOLOGY  
ASSOCIATES, P.A. TO DISMISS THE FIFTH AMENDED COMPLAINT**

Michael P. Matthews (*pro hac vice*)  
FOLEY & LARDNER LLP  
100 N. Tampa Street, Suite 2700  
Tampa, Florida 33602-5810  
(813) 225-4131  
mmatthews@foley.com

Lawrence M. Kraus (*pro hac vice*)  
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lkraus@foley.com

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rkramer@foley.com

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Defendant physician practices Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A. (collectively, the “Physician Practices”) submit this memorandum of law in support of their motion to dismiss the Fifth Amended Complaint (“Complaint” or “Compl.”) of relator Don Hanks (“Relator”) pursuant to Federal Rules of Civil Procedure 12(b)(6), 9(b), and 12(b)(1).

The United States has declined to intervene in this action.

### **INTRODUCTION**

Of the United States, the 50 state Attorneys General that have entered into settlements with drug manufacturer Amgen, Inc., and the eleven relators who have sued Amgen for failure to report drug discounts and rebates, not one of them, other than Relator, has sued the oncology clinics to whom Amgen sold drugs, for a very good reason: the law is clear that these clinics are not required to report discounts and rebates. In 1999, the federal government explicitly “eliminate[ed] the requirement that charge-based buyers report discounts on claims submitted to the Federal programs.” *Medicare and State Health Care Programs*, 64 Fed. Reg. 63,518, 63,527 (Nov. 19, 1999). Relator, in alleging that the Physician Practices violated the False Claims Act (“FCA”) by falsely failing to report drug discounts from 2001 to 2011, simply has the law wrong – his Complaint erroneously cites the *proposed* rule that was *not adopted*, *id.* at 63526, not the *final* rule that *was actually adopted*. *Id.* at 63527.

Relator was the seventh of eleven relators to sue Amgen.<sup>1</sup> The government intervened *as to Amgen* in those eleven actions, and reached a settlement with it in ten actions in 2012.<sup>2</sup>

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<sup>1</sup> *U.S. ex rel. Cantor v. Amgen, Inc.*, No. 04-cv-2511 (E.D.N.Y.); *U.S. ex rel. Piacentile v. Amgen, Inc.*, 04-cv-3983 (E.D.N.Y.); *U.S. ex rel. Osiecki v. Amgen, Inc.*, No. 05-cv-5025 (E.D.N.Y.); *U.S. ex rel.*

However, despite many years of lengthy investigation and litigation concerning Amgen's marketing practices, the government has declined to intervene in this or any other Amgen action as against any oncology clinic. Nor has any of the other nine relators or any state asserted any claims against any clinic. Relator now pursues this non-intervened action against the Physician Practices and the other "Oncology Practice" defendants on his own.

Relator's central claim is that Amgen, seeking to increase its profits from the sales of Aranesp, Neupogen, and Neulasta, engaged in a sales and marketing strategy that would give oncology practices such as the Physician Practices incentives to purchase more Amgen drugs by giving them volume-driven discounts and rebates. According to Relator, Amgen provided discounts on these "Covered Drugs" to oncology practices, but Amgen concealed those discounts from the government in reporting its prices. The result, according to Relator, was to keep government reimbursement rates high while maintaining Amgen's ability to offer increasing discounts to oncology practices as a reward for higher purchase volumes. Relator's theory in pursuing claims is that the discounts and rebates Amgen offered to the oncology clinics induced increased sales and allegedly constituted improper kickbacks under the Anti-Kickback Statute, thus rendering each of the clinics' claims for payment to the government without reporting discounts or rebates a "false claim" under the FCA.

Relator's theory rests on a fundamental misunderstanding of how Medicare claims are billed and reimbursed and on a misreading of the Anti-Kickback Statute safe harbor provision

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*Westmoreland v. Amgen, Inc.*, No. 06-cv-10972 (D. Mass.), *U.S. ex rel. Arriazola v. Amgen, Inc.*, No. 06-cv-3232 (E.D.N.Y.); *U.S. ex rel. Horwitz v. Amgen Inc.*, No. C07-0248 (W.D. Wash.); *U.S. ex rel. Kelly v. Amgen Corp.*, No. 08-cv-4157 (E.D.N.Y.); *U.S. ex rel. Hanks v. Amgen, Inc.*, No. 08-cv-3096 (E.D.N.Y.); *U.S. ex rel. Ferrante v. Amgen, Inc.*, No. 08-cv-3931 (E.D.N.Y.); *U.S. ex rel. Tucker v. Amgen, Inc.*, No. 09-cv-0887 (E.D.N.Y.); and *U.S. ex rel. DJAE Partnership v. Amgen, Inc.*, No. 11-cv-11242 (D. Mass.).

<sup>2</sup> The *Piacentile* case, *supra* n. 1, was not settled and remains pending.

governing discounts and rebates.<sup>3</sup> Medicare’s reimbursement of oncology clinics such as the Physician Practices is not tied to the clinics’ costs, and clinics are not required to report such costs – or any discounts or rebates – in order to receive reimbursement. Medicare and other government health program reimbursement rates are based on Average Sales Prices (“ASP”) reported by drug manufacturers such as Amgen, which are “calculated by totaling all of a manufacturer’s sales to all purchasers in the United States.” Compl. ¶¶ 121-124. As Relator alleges, all clinics and physicians nationwide, including the defendant clinics, are paid Amgen’s reported ASP plus 6% by Medicare. *Id.*

Under Relator’s theory, all buyers of Amgen drugs in the United States could be sued; in fact, Relator’s earlier complaints in this case named hundreds of clinics across the country as defendants. But the law is clear that such buyers cannot be sued for how *Amgen* reports *its* ASP. Indeed, the very anti-kickback safe harbor provision on which Relator purports to rely expressly exempts buyers like the Physician Practices from any obligation to report discounts or rebates received in connection with drug purchases. The law only requires cost-reporting entities to report discounts or rebates, and as Relator himself alleges, “[n]one of the defendant Oncology Practices qualified as a ‘cost reporter.’” Compl. ¶ 143.

In addition to this fatal defect to Relator’s claims, the vast majority of Relator’s allegations are devoid of any specific facts whatsoever concerning the Physician Practices. While Relator, a former sales representative for Amgen, asserts reams of allegations about Amgen, he says almost nothing about the Physician Practices, other than that “on information and belief” they bought Amgen drugs, received discounts or rebates, and sought and received reimbursement

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<sup>3</sup> The Physician Practices’ arguments with respect to Medicare apply equally to other federal healthcare programs referenced in the Complaint, including Medicaid and Tricare. *See* 42 U.S.C. § 1320a-7b(f).

from the government for such drugs. *See* Compl. ¶¶ 35, 36, 41, 44, 56. Apparently lacking any direct knowledge concerning the Physician Practices’ billing, reimbursement, or treatment practices, Relator asserts his allegations on information and belief, lumps all defendants together without differentiation, presents publicly-available background information as factual allegations, and in some instances relies on what he himself acknowledges are “hypotheticals” to allege what the Physician Practices could have done, might have done, or had some incentive to do – not what they actually did. Indeed, Relator fails to allege a single fact concerning any specific claim, false or otherwise, that was actually submitted to Medicare or another government health program. Relator does not and cannot satisfy the requirements of Rule 9(b), which is an additional, independent basis for dismissal. Further, this Court lacks subject matter jurisdiction over this action because all of the essential elements of Relator’s claims were publicly disclosed in numerous lawsuits, government reports and news articles well prior to the filing of this action, and Relator cannot establish that he is an “original source” for any fact alleged in the Complaint or in the prior disclosures.

Therefore, as discussed below, all of Relator’s claims against the Physician Practices, namely, the First Cause of Action under the federal False Claims Act and the Third Cause of Action under the Florida False Claims Act, should be dismissed, with prejudice.

### **FACTUAL BACKGROUND**<sup>4</sup>

#### **Relator’s Allegations About Amgen**

Relator’s central claim is that Amgen, seeking to increase its profits from sales of the Covered Drugs, engaged in a sales and marketing strategy that would give oncology physicians and practices such as the Physician Practices greater incentives to purchase the drug Aranesp.

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<sup>4</sup> The recitation of Relator’s allegations set forth herein are accepted as true for the purposes of this Motion only. *See U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 112 (2d Cir. 2010).

Compl. ¶ 77. Amgen provided these incentives to oncology practices through “Amgen Portfolio Contracts,” written agreements with drug purchasers setting forth the terms of volume-based discounts and rebates. *Id.* In marketing these arrangements, Amgen allegedly informed oncology practices of the profits they could earn by taking advantage of the discounts and rebates. *E.g., id.*

¶ 85. Relator also alleges Amgen failed to account for these discounts and rebates when it reported its ASP and average wholesale price (“AWP”) to the government. *Id.* ¶ 103. Because Medicare fee schedule reimbursement rates for drugs such as the Covered Drugs are calculated based on the ASP (and, prior to 2005, were calculated based on the AWP), Amgen’s alleged failure to report discounts or rebates resulted in an inaccurate AWP or ASP and artificial inflation of the reimbursement rates paid to oncology practices. *Id.* ¶¶ 121-126.

Relator alleges that Amgen informed oncology practices such as the Physician Practices of the “financial benefits” of the Amgen Portfolio Contracts – namely, the ability to increase profit margins by purchasing greater volumes of the Covered Drugs while reducing costs through increased discounts and rebates. *See, e.g., Id.* ¶¶ 34, 150. Relator does not allege that the Physician Practices had any input into, or any knowledge whatsoever concerning, Amgen’s reporting of data to the government concerning its ASP or AWP.

Relator also alleges a range of related “illegal practices” by Amgen, such as the tying of Aranesp purchases to Neupogen and Neulasta purchases (*id.* ¶ 180), provision of off-invoice discounts (*id.* ¶¶ 181-84), use of overfill (*id.* ¶¶ 185-192), “price protection” (*id.* ¶¶ 193-94), provision of free goods (*id.* ¶ 195), “marketing the spread” (*id.* ¶¶ 197-206), “improper” financial incentives (*id.* ¶¶ 207-210), and off-label use of the drugs (*id.* ¶¶ 211-12). None of the cited paragraphs, however, contains a single specific fact supporting that any of the defendants,

including the Physician Practices, actually engaged in the alleged improper practices described or submitted a false claim.

### **Relator's Allegations About the Physician Practices<sup>5</sup>**

Relator's allegations against the Physician Practices are in fact sparse. Relator alleges "on information and belief" the same boilerplate as to each of the Physician Practices: that each clinic "purchased Amgen products" in various amounts, received "a rebate or discount," and "sought and received reimbursement" from the government "in amounts that exceeded the actual cost of these products." *See, e.g.*, Compl. ¶¶ 35, 36, 41, 44, 56. Relator alleges, "on information and belief," that Amgen's failure to report discounts and rebates in its ASP/AWP price reporting "combined with" the defendant clinics' "knowing submission of false and fraudulent claims" to cause the government to overpay for the drugs. *Id.* ¶ 103. Relator's only allegation as to why the Physician Practices' claims were false is that "on information and belief," the Physician Practices did not report receipt of the discounts or rebates in their claims for reimbursement. *Id.* ¶ 104. Relator contends that the Physician Practices' acceptance of discounts and rebates without reporting them to the government constituted illegal kickbacks under the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1395y(a)(1)(A), which Relator asserts "did not qualify for safe harbor treatment" under the provision applicable to discounts and rebates. *d.* ¶¶ 141-46.

As for Amgen's alleged "illegal practices," to the extent Relator alleges that any of the Oncology Practices (as opposed to Amgen) engaged in any conduct at all or submitted false claims as a result, Relator alleges so on information and belief or in a hypothetical or speculative manner. *See, e.g., id.* ¶¶ 183, 196 (unidentified false claims submitted, "on information and

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<sup>5</sup> Relator purports to assert various allegations, mostly upon information and belief, against the "Oncology Practice" defendants, improperly grouping all sixteen defendant oncology practices together. As discussed below, such group pleading fails to satisfy Fed. R. Civ. P. 9(b) and is by itself grounds for dismissal. *See infra*, III.B.

belief”), ¶ 192 (describing a “hypothetical case”). Relator only mentions the Physician Practices specifically twice, alleging (1) that Florida Cancer Specialists, P.L. (“FCS”) had the *potential* to participate in the alleged practices, not that it actually did, *see id.* ¶ 179 (asserting that a FCS physician administered vials containing overfill that “could be recovered” and “could be administered,” allowing the “opportunity” for greater cost recoupment), and (2) that Amgen’s physician roundtable events “often” involved no medical discussions and that an FCS physician and a Gulfcoast Oncology Associates physician accepted honoraria for participating in roundtable events – without alleging what, when, where, or specifically how the alleged honoraria caused the submission of specific false claims. *Id.* ¶ 207.

Relator does not identify a single claim for reimbursement, with particularity or otherwise, let alone any claim that was to any government health program. Nor does Relator assert any facts supporting that the Physician Practices “knowingly” submitted any false claims, among multiple other pleading deficiencies addressed below.

## **ARGUMENT**

### **I. STANDARDS OF REVIEW**

#### **A. Motion to Dismiss Under Federal Rule of Civil Procedure 12(b)(6)**

A motion to dismiss under Fed. R. Civ. P. 12(b)(6) challenges the legal sufficiency of a complaint on its face. To survive such a motion to dismiss, “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). To state such a facially plausible claim, a complaint must contain “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* “[A] plaintiff’s obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the

elements of a cause of action will not do.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks and quoting citation omitted). Legal conclusions are not entitled to an assumption of truth on a motion to dismiss. *See Pension Benefit Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Ret. Plan v. Morgan Stanley Inv. Mgmt., Inc.*, 712 F.3d 705, 717 (2d Cir. 2013) (“We ‘are not bound to accept as true a legal conclusion couched as a factual allegation.’”) (citation and quoting reference omitted); *see also Mortimer Off Shore Servs., Ltd. v. Fed. Rep. of Ger.*, 615 F.3d 97, 114 (2d Cir. 2010) (“Although we must accept as true all of [a complaint’s] allegations...that tenet is inapplicable to legal conclusions, and [t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice.”) (alterations in original) (internal quotation marks and quoting reference omitted).

#### **B. Pleading With Particularity Under Federal Rule of Civil Procedure 9(b)**

Because FCA claims are fraud claims, in order to state a claim a relator must satisfy the heightened pleading requirements of Fed. R. Civ. P. 9(b). *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995). Rule 9(b) requires that a complaint must be pleaded with particularity and must “(1) specify the statements that the [relator] contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Wood ex rel. U.S. v. Applied Research Assocs., Inc.*, 328 Fed. Appx. 744, 747 (2d Cir. 2009) (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994)); *see also U.S. ex rel. Duxbury v. Ortho Biotech Prods. L.P.*, 579 F.3d 13, 29-30 (1st Cir. 2009) (relator must identify the “who, what, where, and when” of the alleged fraud to satisfy Rule 9(b)); *Chen v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282 (S.D.N.Y. 2013) (same). “The purpose of Rule 9(b) is threefold—it is designed to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing,



and to protect a defendant against the institution of a strike suit.” *Wood*, 328 Fed. Appx. at 747 (citing *O’Brien v. Nat’l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991)).

**C. Lack of Subject Matter Jurisdiction Under 31 U.S.C. § 3730(e)(4)**

Federal courts lack subject-matter jurisdiction over FCA actions based on “allegations or transactions” that have been “public[ly] disclos[ed]” in a “criminal, civil, or administrative hearing, in a congressional, administrative or Government Accounting Office report, hearing, audit, or investigation, or from the news media” unless the relator “is an original source of the information.” 31 U.S.C. § 3730(e)(4)(A). To be an “original source,” a relator must have “direct and independent knowledge of the information on which the allegations are based.” 31 U.S.C. § 3730(e)(4) (1986).<sup>6</sup>

A threshold question is therefore whether the FCA bars jurisdiction. *See U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007). The relator bears the burden of demonstrating that federal subject-matter jurisdiction exists. *U.S. ex rel. Phipps v. Comprehensive Cmty. Dev. Corp.*, 152 F.Supp. 2d 443, 449 (S.D.N.Y. 2001) (citing *Malik v. Meissner*, 82 F.3d 560, 562 (2d Cir. 1996)). In considering this issue, the Court should strictly construe the public disclosure bar and resolve any doubts against federal jurisdiction. *See, e.g., U.S. ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 318 (D. Mass. 2009).

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<sup>6</sup> This language in the FCA was first inserted in 1986 and was amended in 2010. *See Patient Protection and Affordable Care Act of 2010*, Pub. L. No. 111-148, § 10104, 124 Stat. 119, 901 (2010). The 2010 amendment is not retroactively applicable to *qui tam* actions pending at the time of amendment. *Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010) (“The legislation makes no mention of retroactivity, which would be necessary for its application to pending cases given that it eliminates petitioners’ claimed defense to a *qui tam* suit.”). Relator’s action was first filed in 2008, and thus the 1986 version of the FCA governs here.

**D. The Elements of a Cause of Action under the False Claims Act**

Relator asserts claims under the FCA provisions that impose liability on a person who:

- (1) knowingly presents, or causes to be presented... a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or]
- (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

31 U.S.C. § 3729(a)(1)-(3).<sup>7</sup>

To state a claim under § 3729(a)(1), a relator must plead that a defendant “(1) made a claim, (2) to the United States government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury.” *U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 695 (2d Cir. 2001). The elements of a § 3729(a)(2) claim are that a defendant (1) made, used, or caused to be made or used a record or statement, (2) that is false or fraudulent, (3) knowing of its falsity, (4) to get a false or fraudulent claim paid or approved by the government. *U.S. ex rel. Pervez v. Beth Isr. Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010); *U.S. ex rel. Colucci v. Beth Isr. Med. Ctr.*, 785 F. Supp. 2d 303, 310 (S.D.N.Y. 2011). Under § 3729(a)(3), a relator must allege that “(1) the defendant knowingly conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States and (2) that one or more of the coconspirators performed any act to effect the object of the conspiracy.” *Colucci*, 785 F. Supp. 2d at 310.

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<sup>7</sup> Some limited portion of Relator’s causes of action may be subject to the 2009 FERA amendments to the FCA, Pub. L. No. 111-148, 124 Stat. 119 (2010), which changed the wording of several of these provisions, but not in any way that is material to this motion.

## **II. RELATOR'S COMPLAINT FAILS TO STATE A CLAIM AND SHOULD BE DISMISSED PURSUANT TO RULE 12(b)(6)**

### **A. Relator's Core Claim Is Based on an Error of Law as the Government in 1999 Eliminated the Requirement that Charge-Based Buyers Like the Physician Practices Report Discounts and Rebates.**

The crux of Relator's limited allegations against the Physician Practices is that they purchased drugs from Amgen at discounted prices or subject to rebates and did not report those discounts and rebates when submitting bills to the government. *See, e.g.*, Compl. ¶¶ 35, 36, 41, 44, 56, 104. According to Relator, the discounts and rebates Amgen offered to the Physician Practices and other defendant clinics induced increased sales and constituted improper kickbacks under the AKS, 42 U.S.C. § 1320-7b. Compl. ¶¶ 141, 205. Relator's theory is that the Physician Practices' submission of claims for payment to the government without reporting discounts or rebates constituted false claims under the FCA. *Id.* ¶¶ 152-53.

Relator's theory is wrong as a straightforward matter of law, as Relator relies on a proposed rule that was never adopted. *Id.* ¶ 142. The Physician Practices submit bills to government programs according to a fee schedule and are *not* required by the final adopted rule to report discounts and rebates in connection with their bills. As a result, even if Relator's allegations concerning the absence of discount and rebate reporting are taken as true for the purposes of this Motion, Relator cannot establish an AKS violation and cannot establish the elements of falsity or scienter necessary to state a claim under the FCA.

#### **i. Relator Cannot Plead Falsity.**

##### **1. The Physician Practices Are Subject to an AKS Safe Harbor.**

Relator's allegations rest on a misreading of the AKS safe harbor provisions, which in fact explicitly permit the very discounts and rebates that Relator alleges violate the FCA. Specifically, under 42 C.F.R. § 1001.952(h) and since before 2001, discounts provided to the

Physician Practices at the time of sale and rebates, the terms of which are fixed and disclosed at the time of sale, do not violate the AKS. Relator relies on Section 1001.952(h)(1)(ii), which provides “[i]f the buyer is an entity which reports its costs on a cost report,” the entity “must fully and accurately report the discount in the applicable cost report.” Yet Relator acknowledges that none of the Physician Practices reports its costs on a cost report. Compl. ¶ 143. Instead, the applicable rule is found at Section 1001.952(h)(iii), which provides that purchasers that are charge-based buyers, like the Physician Practices and the other clinic defendants, are *not* required to report discounts or rebates when submitting bills, only to maintain documentation of such discounts and rebates to be provided upon request. That Section provides:

If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid, or other Federal healthcare programs ... the buyer must comply with both of the following standards—

- (A) the discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and
- (B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller ...

Thus, this safe harbor applies without any requirement to report discounts or rebates to the government, and there can be no AKS violation – and no false claim – where: (1) the buyer is a charge-based buyer, not a cost reporting entity; and (2) the discount is given, or the terms of the rebate are fixed and disclosed in writing, at the time of the sale.

Relator does not allege any facts that would place the Physician Practices outside of this safe harbor provision. On the contrary, Relator explicitly concedes that the Physician Practices are not cost reporting entities, alleging, “[n]one of the Oncology Practices qualified as a ‘cost

reporter.”” Compl. ¶ 143.<sup>8</sup> Relator also concedes that all discounts and rebates provided to the Physician Practices were given or fixed and disclosed in writing at the time of the sale; according to the Complaint, all such discounts and rebates were set forth in advance in the Amgen contracts through which the Physician Practices purchased the Covered Drugs. *See Id.* ¶ 34 (alleging oncology practices signed Amgen Portfolio Contracts containing the relevant discounts and rebates); ¶¶ 86-87 (alleging such contracts disclosed the discount and rebate structures to be offered); ¶ 232 (“Amgen entered into agreements with each of the Defendant Oncology Practices”). For example, paragraphs 233 – 235 of the Complaint quote the fixed rebate percentages in the contract, indicating that the rebates were both fixed and in writing at time of sale. Thus, taking Relator’s allegations as true, the Physician Practices were entitled to the safe harbor protection of Section 1001.952(h)(1)(iii).

Relator mistakenly relies on what he contends is commentary “on the Final Rule,” but which in fact is a quotation from commentary on the “Proposed” rule. *See Compl.* ¶ 142; 64 Fed. Reg. 63,518, 63,526 (Nov. 19, 1999). As indicated in the commentary under the heading “Summary of Proposed Clarifications,” the rule as originally proposed would have excluded from the safe harbor any rebate given to a charge-based buyer covered by paragraph (h)(1)(iii). 64 Fed. Reg. 63,518, 63,526. But Relator fails to point out that *the very next page* of the Federal Register states that, in response to comments received on the proposed rule, the Department of

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<sup>8</sup> Indeed, it is well established that physician practices such as the Physician Practices are charge-based buyers, not cost reporting entities – they bill government healthcare programs by submitting claims according to fee schedules, and do not submit cost reports. *See, e.g.,* Medicare Claims Processing Manual, available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS018912.html>, Ch. 12, § 20 (noting that physicians bill on the basis of a fee schedule); Ch. 17, §§ 10, 20 (setting forth rules for Medicare billing for drugs and biological and distinguishing between drugs provided by hospitals, which are billed and reimbursed pursuant to Medicare’s cost-reporting and prospective payment system, and drugs provided incident to physician services, which are billed pursuant to fee schedules).

Health and Human Services (“HHS”) rejected the rebate exclusion, instead adopting the final rule that included rebates in the safe harbor, as discussed above. As HHS explained:

We are modifying our proposed definition of a “rebate” *to include any discount the terms of which are fixed at the time of sale of the good or service*. This modification will enable us *to extend safe harbor protection to certain charge-based buyers and buyers reimbursed on the basis of fee schedules who obtain rebates*.

64 Fed. Reg. 63,518, 63,527 (emphasis added). Most importantly for purposes of this case, HHS clarified that the final rule eliminated charge-based buyers’ requirement to report discounts:

We are *eliminating the requirement that charge-based buyers report discounts on claims submitted to the Federal programs*; however, we are retaining the requirement that such buyers provide documentation of discounts to the Secretary upon request.

*Id.* (emphasis added). The Final Rule became effective in 1999, before the 2001-2011 time period Relator alleges in his Complaint. Compl. ¶ 2.<sup>9</sup>

In sum, the Physician Practices, as charge-based buyers, could not possibly have falsely failed to report discounts or rebates or violated the AKS as a result, as alleged in the Complaint.<sup>10</sup> Even had Relator identified any alleged claim or certification with particularity, which he did not, he cannot plead the falsity of any such claim or certification because there is no falsity as a matter of law.<sup>11</sup>

## 2. Relator’s Off-Label Promotion Allegations Fail.

Relator alleges that Amgen improperly promoted the Covered Drugs for off-label uses, *Id.* ¶ 112, and “on information and belief” that the Physician Practices prescribed the Covered

<sup>9</sup> In any event, the Final Rule became effective prior to any conceivable claim that could be alleged within the limitations period applicable to this action commenced in 2008. *See* 31 U.S.C. § 3731(b)(1).

<sup>10</sup> Relator’s allegations regarding “marketing the spread,” Compl. ¶¶ 197-206, fail for the same reasons. Relator alleges that the Physician Practices were given volume discounts for the Covered Drugs which allowed the Physician Practices to be “over reimbursed.” *Id.* ¶ 198. Because the Physician Practices had no reporting obligations, their reporting or absence thereof did not impact the AWP, and these allegations likewise fail to state a claim against the Physician Practices as a matter of law.

<sup>11</sup> That the Physician Practices’ contracts with Amgen provide that they “shall comply with any discount reporting obligations they may have,” *Id.* ¶¶ 144, 200, does not create a duty to report discounts to the government where there is otherwise no requirement to do so.

Drugs for off-label uses. *Id.* But Relator does not plead how the Physician Practices’ alleged off-label use resulted in any of them submitting a false claim to the government. While Amgen may be prohibited from promoting off-label uses, providers are not prohibited from using drugs for off-label uses. *See, e.g., In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 415 (E.D.N.Y. 2009) (“[E]ven though it is improper for a drug company to affirmatively merchandize a drug for an off-label use, doctors may voluntarily prescribe FDA-approved medicines for approved and unapproved uses as they believe appropriate in their exercise of their own professional judgment...Some off-label uses of a prescription drug may be medically necessary.”); *U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 U.S. Dist. LEXIS 43438, at \*16 (E.D.N.Y. May 22, 2009) (“[A] physician may prescribe [a drug] for...patient populations that are not included in approved labeling. Such ‘unlabeled’ uses may be appropriate and rational.”); *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989) (“FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.”).

## **ii. Relator Also Cannot Plead Scienter.**

Relator also cannot plead the Physician Practices’ scienter as required by the FCA. To plead an FCA violation based on conduct allegedly in violation of the AKS, a relator must “allege sufficient facts to support an inference or render plausible” that the defendant “acted while knowing that its” conduct “fell outside of the Safe Harbor Provision on which it was entitled to rely.” *U.S. ex rel. Lee v. Corinthian Colls.*, 655 F.3d 984, 997 (9th Cir. 2011). Failure to do so warrants dismissal. *Id.* Here Relator does not allege, nor could he, that the Physician Practices acted while knowing that their conduct fell outside the applicable AKS safe harbor – because it did not, as a matter of law. Accordingly, Relator’s claims with respect to discounts and rebates fail on this ground as well, and the Complaint should be dismissed.

**B. Relator's Conspiracy Claim Based on Amgen's Alleged Failure to Report Discounts or Rebates Also Fails to State a Claim.**

For an FCA conspiracy a relator must allege that (1) the defendant “knowingly conspired with one or more persons” to get a false claim paid and (2) that one or more co-conspirators performed an act in furtherance of the conspiracy. *See Colucci*, 785 F. Supp. 2d at 310; 31 U.S.C. § 3729(a)(3). An essential element, therefore, is “an *agreement* between two or more persons” to defraud the government. *U.S. v. Inc. Vill. of I. Park*, 888 F. Supp. 419, 443 (E.D.N.Y. 1995) (emphasis added). A so-called “hub and spokes” conspiracy additionally requires not only an unlawful agreement between a central “hub” and various “spokes,” but also a “connecting rim,” that is, an agreement between and among the “spoke” participants to further the central goal. *U.S. v. Small*, No. 03 CR 1368, 2005 U.S. Dist. LEXIS 45474, at \*28 (E.D.N.Y. May 27, 2005) (quoting *Kotteakos v. U.S.*, 328 U.S. 750 (1946)).

Relator's “hub and spoke” theory fails because Relator does not allege any agreement among the defendant clinics to participate in Amgen's alleged scheme. Moreover, Relator fails to allege any facts whatsoever establishing any agreement between Amgen and the Physician Practices (or any other clinics) to engage in unlawful activity. While Relator fills much of the Complaint with allegations concerning Amgen's alleged schemes, Relator fails to allege any facts indicating that the Physician Practices knew about the alleged schemes, let alone entered into any agreement to further them.<sup>12</sup> At most, Relator alleges that the Physician Practices had “incentives” to increase their drug purchases as a result of the Amgen contract structure (*e.g.*, Compl. ¶¶ 90, 232), or that they were motivated to earn profits and, therefore, to take advantage

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<sup>12</sup> In fact, Relator's allegations regarding the agreements demonstrate that the Physician Practices did not intend to conceal anything. As alleged, the agreements state that Medicare *will* be notified of discounts. Compl. ¶ 200. Relator also alleges that Amgen specifically told providers *it* would inform Medicare as necessary of all discounts. *Id.* The contract language combined with alleged representations by Amgen demonstrate that the Physician Practices had no reason to know that the discounts would not be reported, and therefore negate the required knowledge.



of discounts offered by Amgen (*e.g.*, *id.* ¶¶ 160, 246).<sup>13</sup> But an incentive to increase profits, without more, does not state a conspiracy (or any other) claim under the FCA. *See, e.g., U.S. ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 528 (6th Cir. 2012) (“Why a business ought to be punished solely for seeking to maximize profits escapes us.”); *Colucci*, 785 F. Supp. 2d at 315 (finding that there was no falsity where relator “alleged nothing more than that [defendant] took steps to maximize its Medicare reimbursements”).

Relator’s allegations boil down to the claim that the Physician Practices knew the discounts and/or rebates they were receiving, not that they had any knowledge of Amgen’s purported misreporting of data relevant to AWP/ASP or any knowledge of the allegedly resulting manipulation of Medicare fee schedules. Without such knowledge, the Physician Practices cannot possibly have “agreed” to any such scheme. Further, Relator alleges that the Physician Practices benefitted from how Amgen reported AWP/ASP. *E.g.*, Compl. ¶ 104. But as Relator alleges, AWP/ASP is calculated based on all sales to all purchasers in the United States. *Id.* ¶ 121. Relator’s erroneous theory therefore proves much too much; under Relator’s view, all purchasers nationwide could be liable under the FCA for how Amgen chose to do its reporting. For all these reasons, Relator’s conspiracy cause of action fails to state a claim.

### III. RELATOR’S ALLEGATIONS DO NOT SATISFY RULE 9(b)

As set forth above, *supra* at I.B, the specificity requirements of Fed. R. Civ. P. 9(b) apply to the FCA, including that a *qui tam* relator must set out specific allegations concerning the who, what, where, when and how of both the underlying fraudulent conduct or scheme and the

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<sup>13</sup> For the reasons discussed in Section III, *infra*, as well as because Relator does not plead the details of any unlawful agreement entered into by the Physician Practices, Relator’s conspiracy allegations also are not pleaded with the specificity required by Fed. R. Civ. P. 9(b). *See Goldberg v. Rush Univ. Med. Ctr.*, 929 F. Supp. 2d 807, 825 (N.D. Ill. 2013) (FCA conspiracy claim must satisfy Rule 9(b)). Relator does not, for example, allege who at the Physician Practices entered into any agreement to defraud the government, or when and where any such agreements were entered.

allegedly false claims or statements actually submitted to the government. In this case, all of Relator's causes of action should be dismissed for failure satisfy Rule 9(b). First, Relator fails to identify any particular false claim that was actually submitted to the government. Second, Relator's allegations against "Defendants" generally without specifying each's role and particular allegations supporting claims against each defendant fail to give the Physician Practices adequate notice under Rule 9(b). Third, Relator has not pleaded any false certification claims with particularity. Finally, Relator's hodgepodge of Amgen's alleged "illegal practices" are not pleaded with particularity as to any of the Physician Practices.

Relator's vague, conclusory, and inflammatory allegations, for example that doctors at the Physician Practices over-prescribed the Covered Drugs and risked patient safety, are exactly the type of unsupported allegations that improperly tarnish reputations while failing to provide specific allegations that Rule 9(b) seeks to prevent. They should be dismissed.

**A. All of Relator's Causes of Action Should Be Dismissed Because Relator Fails to Identify Any Claim Actually Submitted to the Government, with Particularity or Otherwise.**

A false or fraudulent claim is an essential element of a cause of action under 31 U.S.C. § 3729(a)(1), (2), and (3). *See, e.g., Mikes*, 274 F.3d at 695; *Pervez*, 736 F. Supp. 2d at 811; *U.S. ex rel. Finney v. NextWave Telecom, Inc.*, 337 B.R. 479, 489 (S.D.N.Y. 2006) (dismissing FCA conspiracy claim on 9(b) grounds for failure to identify a false claim). "Although 'the Second Circuit has not explained exactly what Rule 9(b) demands of FCA claims,' the weight of authority from district courts within this Circuit is that where an alleged FCA violation involves the submission of a false claim to the Government for reimbursement, the details of that false claim must be pled with particularity." *U.S. ex rel. Moore v. GlaxoSmithKline, LLC*, No. 06 Civ. 6047, 2013 U.S. Dist. LEXIS 165205, at \*8 (E.D.N.Y. Oct. 16, 2013) (quoting *U.S. ex rel.*

*Mooney v. Americare, Inc.*, No. 06-CV-1806, 2013 U.S. Dist. LEXIS 48398 (E.D.N.Y. Apr. 3, 2013)). A relator must identify the particular false claims for payment that were submitted to the government by (1) identifying which of the claims that the defendant submitted were false and (2) providing a factual basis to support the assertion that claims were actually submitted to the government. *See U.S. ex rel. Kester v. Novartis Pharms. Corp.*, No. 11 Civ. 8196, 2014 U.S. Dist. LEXIS 81180, at \*18 (S.D.N.Y. June 10, 2014). This includes “details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices.” *Polansky*, 2009 U.S. Dist. LEXIS 43438, at \*11-12. Relator “cannot meet even a bare-bones Rule 9(b) test” where “allegations of fraudulent billing are primarily conclusory summations and assumptions or allegations based solely on information and belief.” *See, e.g., U.S. ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 86-87 (D. Conn. 2006). This particularity requirement applies to all FCA cases, including allegations of AKS violations and false certification claims. *See, e.g., Moore*, 2013 U.S. Dist. LEXIS 165205, at \*13.

Here, Relator does not identify *even a single* false claim or plead any of the details of any false claims actually submitted to Medicare by the Physician Practices, either by date, claim number, content, quantity, or amount. He likewise does not plead who at the Defendants’ practices submitted any false claims or on what dates in particular any false claims were submitted. All Relator alleges as to any of the Physician Practices is the same boilerplate recitation that “on information and belief,” the Physician Practices “sought and received reimbursement from Government Healthcare Programs for administration of the Covered

Drugs.” *See, e.g.*, Compl. ¶¶ 35-36, 41, 44, 56. This conclusory allegation, based on information and belief, clearly does not suffice. *See, e.g., Smith*, 415 F. Supp. 2d at 86.

In fact, New York District Courts have recently dismissed FCA claims on strikingly similar allegations. The relator in *Moore*, 2013 U.S. Dist. LEXIS 165205, alleged that GlaxoSmithKline (“GSK”) improperly induced physicians to issue prescriptions by paying kickbacks in the form of, *inter alia*, sham honoraria and excessive payments for advising. *Id.* at \*2, \*5. Moore alleged that these kickbacks caused the claims and certifications of compliance with the AKS submitted by the physicians to be false. *Id.* at \*3-4. The Eastern District of New York (Cogan, J.) dismissed on 9(b) grounds because Moore did not allege the details of any specific claims for payment or specific certifications signed by specific physicians. *Id.* at \*13. Instead, Moore alleged the dollar amount of the drugs sold in a given time period and that about 80% of the total sales for the product was reimbursed by Medicare. *Id.* at \*11. The court found that this allegation was “vague” and amounted to nothing more than an allegation “that the submission of a false claim is merely conceivable or even likely,” which did not satisfy Rule 9(b). *Id.* at \*13-14. As in *Moore*, Relator here does not identify any claim that was actually submitted or any specific facts to indicate false claims were submitted, and simply alleging amounts of drugs sold does not suffice.

Similarly, the Southern District of New York recently dismissed a relator’s claims against various pharmacies based on relator’s failure to specifically allege claims submitted to the government. *Kester*, 2014 U.S. Dist. LEXIS 81180, at \*22-23. The relator in *Kester* alleged that the pharmacies had received kickbacks in exchange for encouraging physicians to prescribe certain drugs, *Id.* at \*8-9. Relator did not provide any specifics related to any claims submitted, instead alleging that all prescriptions submitted during a period of time were false. *Id.* at \*23-25.

The court found such general allegations “vague and unhelpful” and dismissed the complaint. *Id.* Because Relator here likewise asserts generally that every claim for the Covered Drugs was a false claim, without providing any specific details of any claim actually submitted to the government, all of Relator’s claims should be dismissed.

**B. Relator’s Allegations Concerning All “Defendants” or All “Oncology Practices” Also Do Not Satisfy the Requirements of Rule 9(b).**

A relator does not adequately plead the “who” in compliance with Rule 9(b) by lumping multiple defendants together in his allegations of fraud. *See, e.g., Wood*, 328 Fed. Appx. at 749-50 (complaint’s “vague or generalized allegations as to a given defendant’s involvement” or complete lack of specifics as to a given defendant’s involvement did not satisfy Rule 9(b)); *Lee*, 655 F.3d at 997-98 (affirming dismissal on Rule 9(b) grounds); *Hayduk v. Lanna*, 775 F.2d 441, 444-45 (1st Cir. 1985) (failure to differentiate “apprises none of the defendants of the individual charges against them” and does not satisfy Rule 9(b)). A relator cannot simply “lump multiple defendants together” without specifying which defendant committed which wrong. *Lee*, 655 F.3d at 997-98. Instead, a relator must “inform each defendant separately of the allegations surrounding [the defendant’s] participation in the fraud.” *Id.*

The vast majority of Relator’s allegations refer to all “Defendants” or “Oncology Practices” collectively and do not allege any specific fraudulent conduct by any individual Defendant. The Physician Practices are thus left to speculate how these various allegations pertain to them, if at all. This is exactly the type of vague pleading that Rule 9(b) is designed to prevent. *U.S. ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1259 (D.C. Cir. 2004) (relator must plead enough detail that a defendant can “defend against the charge and not just deny that they have done anything wrong”) (internal quotation marks and quoting citation omitted); *Wood*, 328 Fed. Appx. at 747 (one purpose of Rule 9(b) is to give a defendant adequate

notice of the claims against it). The Complaint should be dismissed on this basis as well.

**C. Relator Fails to Plead Any False Certification Claim with Particularity.**

There are three types of potentially false claims under the FCA: (1) factually false claims; (2) express false certifications; and (3) implied false certifications. *Mikes*, 274 F.3d at 696-97.

Relator does not allege factual falsity, and to the extent he is attempting to pursue a false certification claim for either implicitly or explicitly certifying compliance with the AKS, he has failed to plead such a claim with the required particularity. Conclusory allegations that a provider falsely certified compliance with a federal statute such as AKS are not enough; instead, Rule 9(b) requires a relator to allege “specific details of an actual Medicaid/Medicare provider certification form signed by a particular physician.” *Moore*, 2013 U.S. Dist. LEXIS 165205, at \*13. Here, Relator does not identify any false certification form even generally, much less a particular certification form signed by a particular physician. This does not satisfy Rule 9(b).

Relator also cursorily alleges that the Physician Practices failed to comply with a standard of care by choosing to prescribe Aranesp rather than Procrit. Compl. ¶¶ 110, 163, 180. To the extent Relator is attempting to assert an implied false certification claim based on these allegations, that claim fails as well. Relator does not plead the details of any such alleged false certification or even what federal rule or regulation the Physician Practices supposedly failed to comply with. By raising these inflammatory allegations about standards of care, Relator seeks to utilize the FCA for the “federalization of medical malpractice” – exactly what the Second Circuit sought to avoid in *Mikes*. *Mikes*, 274 F.3d at 700; *see also Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1047 (N.D. Ill. 1998) (disputes regarding “professional judgment as to an applicable standard of care” is not a proper matter for FCA suit). Violations of standards of care that are not prerequisites to payment or expressly tied to government payment are not false

claims. *Chesbrough v. VPA P.C.*, 655 F.3d 461, 468 (6th Cir. 2011) (dismissing FCA allegations of a violation of a “standard of care” where Medicare did not expressly require compliance with any such industry standard as a condition of payment). Here, Relator has not alleged what standard the Physician Practices supposedly violated, much less how any such standard was a condition of payment. Relator therefore does not state a false certification claim based on the Physician Practices’ care decisions, and any such allegations should be dismissed.

**D. The Overfill and Free Sample Allegations Should Be Dismissed Because Relator Only Alleges this Conduct Hypothetically.**

Relator explicitly concedes that the scheme he alleges relating to overfill, again on “information and belief,” is “hypothetical.” Compl. ¶¶ 190-92.<sup>14</sup> Relator alleges only that the overfill medication “can be” administered to patients, Compl. ¶ 185, and “could be” billed to Medicare, not that either actually occurred, much less who billed Medicare, in what amount, and on what date. *Id.* ¶¶ 179, 189.<sup>15</sup> Likewise, Relator alleges that Amgen gave free samples to unidentified physician practices, who were then “free to” administer and charge payers for the samples – not that any Physician Practice actually did charge anyone for them, much less who, when, or for how much. Compl. ¶¶ 195-96. An allegation of a possibility that a defendant “could” have engaged in a practice without any factual allegations that the defendant did in fact do so is deficient under Rule 9(b). *See Wood*, 328 Fed. Appx. at 746-47 (speculative allegation of a “possibility” does not satisfy Rule 9(b)); *U.S. ex rel. Walsh v. Eastman Kodak Co.*, 98 F. Supp. 2d 141, 147 (D. Mass. 2000) (Rule 9(b) was not satisfied by allegations “set[ting] out a methodology by which the vendors might have produced false invoices...[without citing a single

<sup>14</sup> As only one representative example, in paragraph 190 Relator pleads, “[f]or example, *assume* the case of a *hypothetical* 500 mcg vial of Aranesp[.]” (Emphases added). Such assumptions and hypotheticals do not satisfy Rule 9(b), and the Complaint is replete with them.

<sup>15</sup> Impugning the reputation of Dr. Harwin based on such generalities violates one of the basic rationales for Rule 9(b), and is improper. *See Wood*, 328 Fed. Appx. at 747 (Rule protects “defendant’s reputation from improvident charges of wrongdoing”).

false claim arising from an allegedly false invoice”). Even under the less stringent Rule 12(b)(6) standard, a complaint must be dismissed where the facts suggest “the mere possibility of misconduct.” *Ashcroft*, 556 U.S. at 679. Such is the proper result here.

**E. Relator Does Not Plead the Details of the Physician Practices’ Participation in Any Other Alleged Amgen Scheme.**

Relator’s Complaint is full of generalities and conclusory statements relating to numerous alleged false schemes Amgen supposedly engaged in, but none of those alleged schemes are pleaded with particularity sufficient to satisfy Rule 9(b), much less which of the defendant clinics allegedly engaged in them, when, and how. *See Moore*, 2013 U.S. Dist. LEXIS 165205, at \*12-13 (to satisfy Rule 9(b) relator must plead both the underlying fraudulent scheme or conduct and the submission of false or fraudulent claims with particularity).

Relator never identifies a specific date anywhere in his Complaint for any of his allegations, instead simply asserting that the conduct at issue took place in the ten-year period between 2001 and 2011. Compl. ¶ 2; *see, e.g., U.S. ex rel. Barmak v. Sutter Corp.*, No. 95 CV 7637, 2002 U.S. Dist. LEXIS 8509, at \*13-14 (S.D.N.Y. May 13, 2002) (noting that to satisfy Rule 9(b), “[a]t a minimum, this means the relevant dates of the alleged fraud must be articulated.”).

In addition, Relator fails to plead the who, what, where, when, why, and how for much of the conduct he alleges was fraudulent:

- **Price Protection:** Relator alleges that after Amgen increased prices, it allowed current customers to purchase the Covered Drugs at the old price for a period of time and that therefore claims submitted to Medicare for reimbursement were false because Medicare relied on the ASP reported by Amgen. Compl. ¶¶ 193, 195. Relator fails to allege any details of this conduct, including when price increases took place, the difference between any old and new prices, which physicians used the “old” prices, and any patients prescribed drugs at old prices – or why Amgen’s ASP reporting is the Physician Practices’ responsibility.



- **Marketing the Spread:** Relator essentially alleges that Amgen’s “marketing the spread” provided defendants volume discounts, causing them to be “over-reimbursed.” Compl. ¶ 198. Relator alleges that the drug purchasing decisions of FCS, Gulfcoast Oncology Associates, and other Physician Practices were “heavily influenced” by the practice of marketing the spread “[b]ased on statements made to Relator by representatives of the defendants.” *Id.* ¶ 202. Relator does not allege any details of those statements, such as what was said, who made them, and when they were made.<sup>16</sup> Again, Relator also fails to allege how any of this resulted in any clinic filing a false claim, where ASP reporting is not the Physician Practices’ responsibility.
- **Honoraria:** Relator alleges that Amgen provided Physician Practice physicians with honoraria for roundtable events that “often” did not involve medical discussions or only “minimal discussion.” Compl. ¶¶ 207-10. Relator identifies Dr. Jeffrey Paonessa and Dr. Joel Stone of Gulfcoast Oncology as physicians who supposedly accepted what Relator calls “sham” honoraria, *id.* ¶ 207, but he pleads no details to support why these doctors’ honoraria were a “sham,” when the honoraria was given, what the doctors did to receive the honoraria, or how this caused the submission of a false claim to the government. Rule 9(b) does not permit a conclusory allegation of a “sham” without details supporting the charge.
- **Overprescribing or Excessive Dosing:** Relator alleges that defendants prescribed the Covered Drugs with increased frequency and in higher doses than were necessary in order to earn a greater profit. *See, e.g.*, Compl. ¶¶ 104; 109; 173-74; 245. He then alleges that, because the Covered Drugs had some adverse side effects and negative outcomes, overprescribing harmed or “may cause serious harm” to some patients. *Id.* ¶¶ 162; 166; 204. However, Relator fails to allege, *inter alia*, specific examples of any instance in which a physician prescribed the Covered Drugs unnecessarily or at an excessively high dose, any patient that was provided a Covered Drug who did not actually need the drug or who did not need the drug at as high of a dose as was prescribed, any physician who supposedly unnecessarily prescribed the drug, any patient who was supposedly harmed, or how any of this was caused by a desire for profit. Moreover, it is particularly scurrilous to allege – without any specifics – that physicians would put their patients at risk in pursuit of profit.<sup>17</sup>

<sup>16</sup> Relator identifies by name only Amgen employees who supposedly told Relator to market the spread. This does not satisfy Rule 9(b) as to the Physician Practices. *Wood*, 328 Fed. Appx. at 749 (“vague or generalized allegations as to a given defendant’s involvement” did not satisfy Rule 9(b)).

<sup>17</sup> As discussed above, Relator’s off-label use allegations do not state a claim. Even if they could, however, Relator’s allegations do not satisfy Rule 9(b). Relator does not name any physician who prescribed the Covered Drugs for an off-label use, any patient prescribed the Covered Drugs for an off-label use, when or where and off-label prescription was written, or the content of any off-label prescription. Relator also does not identify any claim for payment submitted to Medicare for any drugs prescribed for off-label uses or the time, place, or content of any such claims.

- **Medical Necessity:** Similarly, Relator alleges that the Physician Practices prescribed Covered Drugs to patients for whom that treatment was not medically necessary. *See, e.g.*, Compl. ¶¶ 109, 152; 169; 172-73; 204; 232; 239; 247. Relator does not provide any details regarding specific instances or patients or why such treatment was not medically necessary, including any patient who received unnecessary treatment, any physician who supposedly prescribed medically unnecessary treatment, any prescription that was unnecessary, or the time, place or content of any supposedly unnecessary prescription.

Rule 9(b) therefore requires dismissal of Relators' claims, which should be with prejudice. "Dismissal with prejudice is appropriate under Rule 9(b) where there is a good reason to deny the motion, including when such leave would be futile." *U.S. v. Dialysis Clinic, Inc.*, No. 09-cv-00710, 2011 U.S. Dist. LEXIS 4862, at \*63 (N.D.N.Y. Jan. 19, 2011) (quoting reference and internal quotation marks omitted). Here, Relator has already had five opportunities to amend his complaint and has still failed to plead with particularity. He has not been employed by Amgen since May 23, 2007 (Compl. ¶ 20); therefore there is no reason to believe he will be able to provide any more detail than he has already set forth. *See Dialysis Clinic*, 2011 U.S. Dist. LEXIS 4862, at \*65 (dismissing on Rule 9(b) grounds with prejudice where relator had amended complaint twice and relator's employment had ended two years prior, thereby making it "highly unlikely" he would be able to plead with particularity); *U.S. ex rel. Smith v. N.Y. Presbyterian Hosp.*, No. 06 Civ. 4056 (NRB), 2007 U.S. Dist. LEXIS 53826, at \*27-28 (S.D.N.Y. Jul. 18, 2007) (granting dismissal with prejudice where relator ceased being affiliated with any defendant years before the motion because that made it "highly unlikely that he would be able to plead fraud with sufficient[] particularity even if granted leave to amend"). It is similarly highly unlikely here that after six years and six complaints Relator will be able to come up with additional facts that would state a viable claim against the Physician Practices, and dismissal should be with prejudice.

#### IV. THE COURT LACKS SUBJECT MATTER JURISDICTION

The FCA’s public disclosure bar, 31 U.S.C. § 3730(e)(4), is intended to discourage “parasitic lawsuits by those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud.” *U.S. ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992). Relator is the seventh of eleven relators to bring an FCA claim based on Amgen’s alleged scheme to increase drug sales by providing allegedly undisclosed price incentives to prescribing physicians.<sup>18</sup> Relator brings no new facts to light in his belated attempt to assert these claims; his only contribution is a novel (albeit incorrect) legal theory that the Physician Practices may be held liable for Amgen’s alleged inflation of Medicare reimbursement rates. Relator is therefore not a true whistleblower. His claims are based on allegations or transactions that have been previously disclosed, and he is not an original source.

To determine whether a relator’s claims are prohibited by the FCA’s public disclosure bar, the Court must first decide whether there was a public disclosure of the information. *See, e.g., Id.* at 322-23 & n.3. If there was a public disclosure, the Court must then determine whether relator qualifies as an “original source.” *U.S. ex rel. Kreindler & Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1158 (2d Cir. 1993). Relator fails both of these prongs.

##### A. The Essential Elements of Relator’s Claims Were Publicly Disclosed Prior to the Filing of This Action.

Where “‘all the essential elements of the alleged fraud’ are disclosed,” a *qui tam* action is barred if it is “based *in any part* upon publicly disclosed allegations or transactions” unless the relator is an original source. *U.S. ex rel. Monaghan v. N.Y.C. Dep’t of Hous. Pres. & Dev.*, No. 09 CV 6547, 2012 U.S. Dist. LEXIS 130884, at \*15 (S.D.N.Y. Sept. 7, 2012) (emphasis added)

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<sup>18</sup> See *supra*, n. 1 (listing prior cases).

(citing *U.S. ex rel. Kirk v. Schindler Elevator Corp.*, 437 Fed. Appx. 13, 17 (2d Cir. 2011), *rev'd on other grounds*, 131 S. Ct. 1885 (2011)). The public disclosure bar applies even if the complaint is not based “solely” on public material. *Kreindler*, 985 F.2d at 1158. To be “based upon” a prior public disclosure a relator’s allegations need only be “substantially similar” to the prior disclosure. *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 920 (2d Cir. 2009). The “based upon” inquiry is designed to be a “quick trigger” analysis, *U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp.*, 498 F. Supp. 2d 25, 47 (D.D.C. 2007), and the standard to establish a prior disclosure “is not intended to be difficult to meet,” *U.S. ex rel. Unite Here v. Cintas Corp.*, No. C 06-2413 PJH, 2007 U.S. Dist. LEXIS 98776, at \*35 (N.D. Cal. Dec. 21, 2007).

Further, the elements of the fraud allegation can come from multiple sources that, considered as a whole, are sufficient to “set the government squarely on the trail of fraud such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer.” *In re Pharm. Indus. AWP Litig.*, 538 F. Supp. 2d 367, 383 n.10 (D. Mass. 2008) (citations omitted) (holding prior complaints asserting inflation of AWP sufficient to bar instant suit on the same grounds, even though different defendants were named in prior suits); *see also U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg’l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004); *Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004).

Thus, in *Chen v. EMSL Analytical, Inc.*, 966 F. Supp. 2d 282 (S.D.N.Y. 2013), the relator’s claims alleging that certain asbestos air testing companies violated the FCA by submitting false test reports were barred because the allegations in the complaint were substantially similar to the allegations and transactions that had been publicly disclosed in earlier criminal indictments and news articles. Even though the earlier disclosed information related to

different asbestos companies than the defendants, the Court held that the prior disclosures were “sufficient to set the government squarely upon the trail of the alleged fraud,” and dismissed. *Id.* at 298 (citing *In re Natural Gas Royalties*, 562 F.3d 1032, 1041 (10th Cir. 2009)).

Here, the “essential elements” of Relator’s various claims are that Amgen engaged in a scheme to increase its profits by failing to include discounts, rebates and other price incentives when it reported data on AWP and ASP, which in turn falsely inflated the reimbursement rates that government healthcare providers paid to Amgen customers. Each and every one of these allegations was disclosed in prior litigation, in the news media, and by the government itself years prior to Relator’s filing his original complaint.

As Relator’s own Complaint demonstrates, allegations substantially similar to Relator’s allegations regarding alleged manipulation of AWP and alleged over-prescription of Covered Drugs for profit had been disclosed in both the news media and in publicly filed litigation. *See* Compl. ¶ 106 (citing a 2007 *New York Times* article on Amgen’s alleged inducement of physicians to overprescribe Aranesp); ¶ 184 (noting that lawsuits filed as early as 2001 had alleged that Amgen fraudulently inflated ASP) (citing *In re Pharm. Indus. Average Wholesale Price Litig.*, M.D.L. No. 1456, No. 01-cv-12257 (D. Mass.)).

Numerous other litigations, government reports, and news reports also disclosed substantially similar allegations. For example, in *Citizens for Consumer Justice, et al. v. Abbott Laboratories, Inc.*, Case No. 1:01-cv-12257 (D. Mass. filed Dec. 19, 2001), plaintiffs alleged RICO and other claims against Amgen and other pharmaceutical companies, alleging that the pharmaceutical companies engaged in a fraudulent scheme to “induce healthcare providers to

prescribe the drugs they manufacture.” *Citizens Complaint* ¶ 95.<sup>19</sup> The *Citizens Complaint* further alleged that the pharmaceutical companies:

grossly inflated the average wholesale price for Covered Drugs, sold the drugs to providers at a far lower price, encouraged health care providers to fraudulently charge Medicare and Medicare Beneficiaries at the AWP amount and also encouraged providers to bill for so-called “free samples.”

*Id.* ¶ 96; *see also id.* ¶ 99 (alleging that inducements included “volume discounts, rebates, off-invoice pricing, and free goods, including gifts of cash and other items of value directly to health care providers); ¶ 24 (including Amgen, and its sales of Neupogen, in the allegations); *compare* Compl. ¶¶ 77, 80, 102-104, 120, 154, 237, 250.

Two years later, in *County of Suffolk v. Abbott Laboratories, Inc.*, No. 2:03-cv-00229 (E.D.N.Y. filed Jan. 14, 2003), plaintiff Suffolk County alleged that Amgen and other companies violated RICO and other statutory and common law by engaging in a similar scheme to manipulate the AWP for certain drugs. *See County of Suffolk Complaint* (Kramer Decl. Ex. B), ¶ 2 (alleging drug companies “conspired” with providers to further AWP scheme), ¶¶ 108-112 (alleging details of AWP scheme), ¶¶ 78-82, 155, 161, 187 (alleging use of discounts, rebates, and free goods as part of the alleged scheme), ¶ 82 (alleging drug companies improperly “marketed the spread”). The Westchester County government alleged similar claims against Amgen and others in *County of Westchester v. Abbott Laboratories, et al.*, No. 7:03-cv-06178 (S.D.N.Y. filed Aug. 18, 2003). *See Westchester County Complaint* (Kramer Decl. Ex. C), ¶¶ 1-18, 24, 54-64, 76-116, 128-135 (alleging improper inflation of AWP, “marketing the spread,” and provision of “illegal kickbacks to providers,” including through discounts and rebates).<sup>20</sup>

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<sup>19</sup> A copy of the *Citizens* complaint is attached as Exhibit A to the Declaration of Rachel Kramer (the “Kramer Decl.”) submitted herewith.

<sup>20</sup> Additional cases disclosing Amgen’s alleged manipulation of AWP are listed in the Kramer Declaration, ¶ 3.

The Office of the Inspector General (“OIG”) of the Department of Health and Human Services itself published reports prior to Relator’s action concerning pharmaceutical companies’ potential manipulation of AWP to maximize customers’ profits<sup>21</sup> and specifically concerning Amgen’s reporting of ASP for Aranesp.<sup>22</sup>

Relator’s ancillary allegations were also publicly disclosed prior to this action, including Amgen’s tying of Aranesp purchases to purchases of Neupogen and Neulasta (Compl. ¶¶ 111, 180) and allegations that Amgen induced health care providers to overprescribe Covered Drugs (e.g., *id.* ¶¶ 213-217). *See, e.g., Ortho Biotech Prods., L.P. v. Amgen Inc.*, No. 05-cv-04850 (D.N.J. filed Oct. 11, 2005) (Kramer Decl. Ex. E); *Sheet Metal Workers Nat’l Health Fund v. Amgen, Inc.*, No. 07-cv-5295 (D.N.J. filed Nov. 2, 2007) (Kramer Decl. Ex. F); Alex Berenson and Andrew Pollack, “Doctors Reap Millions for Anemia Drugs,” *N.Y. Times*, May 9, 2007, <http://www.nytimes.com/2007/05/09/business/09anemia.html> (Kramer Decl. Ex. G).

These public disclosures, which mirror the allegations in the Complaint, were more than sufficient to “set the government upon the trail” of the purported fraud alleged in the Complaint.

#### **B. Relator Is Not An Original Source.**

Relator cannot avoid the public disclosure bar by establishing himself as an “original source.” To qualify as an “original source,” a relator must have “direct and independent knowledge of the information on which the allegations are based.” 31 U.S.C. §§ 3730(e)(4)(B); *see Kirk*, 437 Fed. Appx. at 18 (in order for a relator’s knowledge to be “direct and independent,” the relator must be the “‘source of the core information’ upon which the qui tam

<sup>21</sup> See HHS, OIG, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23,731-01, 23,723 (May 5, 2003) (“If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated . . .”).

<sup>22</sup> See HHS, OIG, *Audit of Amgen USA, Inc.’s Second Quarter 2005 Average Sales Price Calculation for Aranesp* (Jul. 2007). (Kramer Decl. Ex. D).

complaint is based”) (quoting reference omitted); *Rockwell Int’l Corp. v. U.S.*, 549 U.S. 457, 470-71 (2007) (requiring “direct and independent knowledge” of all of the “information upon which the relators’ allegations are based”). In order to avoid the public disclosure bar, a relator must be not only the original source of the allegations in his complaint, but also the original source of the prior public disclosures. *U.S. v. N.Y. Med. Coll.*, 252 F.3d 118, 121 (2d Cir. 2001) (“[A] qui tam plaintiff does not satisfy the [original source] requirement if a third party is the source of the core information upon which the qui tam complaint is based.”) (citation and quotation omitted); *Kirk*, 437 Fed. Appx. at 18.

Here, six prior relators, multiple other litigants, the government, and the news media, among others, were the sources of the public disclosures, not Relator.

Relator’s only contribution is a new legal theory that the Physician Practices violated the FCA by failing to report the price incentives allegedly received from Amgen. But a relator’s attempt to take publicly-available information and “formulate [a] novel legal theory of fraud is irrelevant to the question of whether the material transactions giving rise to the alleged fraud were already disclosed in the public domain in the first place.” *A-1 Ambulance Serv., Inc. v. Cal.*, 202 F.3d 1238, 1245 (9th Cir. 2000). Nor does a relator become an original source simply because he is the first to label a defendant’s publicly known conduct as “fraud.” *See, e.g., Cal. ex rel. Bates v. Mortg. Elec. Reg.Sys., Inc.*, No. 10-CV-01429, 2011 U.S. Dist. LEXIS 29829, at \*13-14 (E.D. Cal. Mar. 10, 2011), *aff’d*, 694 F.3d 1076 (9th Cir. 2012) (rejecting relator’s argument that he was an original source because he was the first person to label defendants’ conduct as “fraud” and comprehend the significance of the public disclosures) (citing reference omitted).



Moreover, as discussed above, *supra* at III, Relator's allegations about the Physician Practices are anything but "direct and independent." On the contrary, the vast majority of Relator's allegations are asserted on information and belief, in general terms, or in the hypothetical. Relator does not and cannot allege any basis for his purported knowledge concerning how and whether the Physician Practices prescribed, billed, or were reimbursed for the Covered Drugs. Moreover, even with respect to his allegations about Amgen, Relator cannot claim to have direct and independent knowledge of any Amgen conduct following his termination in May 2007. *See* Compl. ¶ 20.

Relator therefore cannot overcome the public disclosure bar, and his claims should be dismissed for lack of subject matter jurisdiction.

#### **V. THE STATUTE OF LIMITATIONS BARS RELATOR'S ACTION IN PART**

While Defendants are somewhat hampered by the continuing seal of Relator's first two complaints and therefore reserve the right to assert additional statute of limitations challenges, it is clear from the current Complaint that at least some of Relator's claims are time-barred.<sup>23</sup> The FCA's statute of limitations is six years. 31 U.S.C. § 3731(b)(1). Relator filed his initial complaint under seal in 2008, and the docket shows a date of filing of July 28, 2008. Therefore, the FCA's statute of limitations bars Relator's action at least as to any claims prior to July 28, 2002. Since the Complaint seeks to impose liability for claims made from 2001-2011, the Complaint should be dismissed, at least in part, because some claims are barred by the statute of limitations. Second, Relator's claims should, based on Relator's own allegations, be limited to

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<sup>23</sup> A statute of limitations argument is properly addressed on a motion to dismiss here, since the deficiency is plain on the face of the complaint. *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 74-75 (2d Cir. 1998) ("An affirmative defense may be raised by a pre-answer motion to dismiss under Rule 12(b)(6), without resort to summary judgment procedure, if the defense appears on the face of the complaint."). On July 25, 2014, certain of the Oncology Practices moved to unseal those versions of Relator's complaint which remain sealed, which Motion [Dkt. # 118] remains pending.

claims submitted in 2004 or later. Relator asserts that the Amgen marketing practices that allegedly led to FCA violations started in 2004. Compl. ¶¶ 77, 230. Because, according to Relator's own allegations, no kickbacks or other alleged fraudulent conduct occurred prior to 2004, Relator's Complaint should be limited in time to claims filed in 2004 or later.<sup>24</sup>

Finally, Relator's "hub and spoke" conspiracy claim, to the extent not dismissed on the other grounds set forth above, should be limited in time to claims submitted on or after May 30, 2008, six years after Relator first raised this claim in his Fifth Amended Complaint filed on May 30, 2014. Dkt. 51. "[C]ourts have declined to apply the relation back doctrine to allow the addition of new claims for relief based on transactions or events not included in the original pleading." *Grace v. Rosenstock*, 169 F.R.D. 473, 481 (E.D.N.Y. 1996), *aff'd*, 228 F.3d 40 (2d Cir. 2000). Relator's "hub and spoke" conspiracy allegations and allegations regarding the Amgen Portfolio Rebate Program Letter Agreements appear for the first time in Relator's Fifth Amended Complaint and therefore do not relate back to earlier versions of Relator's complaint. *See Cent. Hudson Gas & Elec. Corp. v. Combustion Eng'g. Inc.*, No. 86 Civ. 3061, 1989 U.S. Dist. LEXIS 8509, at \*11 (S.D.N.Y. July 26, 1989) (refusing to allow relation back where "the claims asserted in the Amended Complaint arise out of an agreement distinct from that which was the basis for the causes alleged in the Original Complaint"). This claim is therefore subject to a six-year statute of limitations from the date of the Fifth Amended Complaint, and all claims prior to May 30, 2008 are barred. To the extent the unsealing of Relator's first two complaints

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<sup>24</sup> Because all or part of Relator's Fifth Amended Complaint may not relate-back to any of Relator's earlier filed complaints, it is possible that allegations based on conduct prior to May 30, 2008 would be untimely. *See U.S. v. Baylor Univ. Med. Ctr.*, 469 F.3d 263, 270 (2d Cir. 2006); *Hayes v. Dep't of Educ. of N.Y.C.*, No. 12-cv-1357, 2014 U.S. Dist. LEXIS 68311, at \*26 (S.D.N.Y. May 16, 2014) (quoting *Baylor*, 469 F.3d at 270 for the proposition that "because 'notice...is the touchstone of [Rule 15(c)(1)(B)] relation-back,' it is simply not permissible for amended pleadings to relate back to original complaints filed under seal pursuant to § 3730(b)(2).").

reveal that other allegations in this case were added after the original complaint was filed in 2008, Defendants may identify additional claims barred by the statute of limitations.

**VI. RELATOR'S THIRD CAUSE OF ACTION UNDER THE FLORIDA FALSE CLAIMS ACT SHOULD BE DISMISSED**

The Florida False Claims Act is based on and largely mirrors the language of the federal FCA; therefore, courts have imposed the same pleading standards on Florida FCA claims as federal FCA claims. *See, e.g., U.S. ex rel. Schubert v. All Children's Health Sys., Inc.*, No. 8:11-cv-1687-T-27EAJ, 2013 U.S. Dist. LEXIS 53932, at \*14-15 (M.D. Fla. Apr. 15, 2013). The analysis for the federal FCA applies equally to the Florida FCA claims and compels dismissal of the Florida claims if the federal claims are dismissed. *See, e.g., U.S. ex rel. Romanosky v. Aggarwal*, No. 6:03-cv-117, 2005 U.S. Dist. LEXIS 46098, at \*13-14 (M.D. Fla. Feb. 20, 2005); *U.S. ex rel. Heater v. Holy Cross Hosp., Inc.*, No. 03-62097-CIV-COHN/SNOW, 2007 U.S. Dist. LEXIS 63706, at \*13-14 (S.D. Fla. Aug. 29, 2007). Relator's Third Cause of Action for a violation of the Florida FCA should therefore be dismissed for the same reasons as Relator's federal false claims allegations.

**CONCLUSION**

For the foregoing reasons, the Court should grant the Physician Practices' Motion to Dismiss in full and dismiss all of Relator's claims with prejudice.

Dated: New York, New York  
August 1, 2014

Respectfully submitted,

FOLEY & LARDNER LLP

By: s/Lawrence M. Kraus  
Lawrence M. Kraus (*pro hac vice*)  
111 Huntington Avenue, Suite 2500  
Boston, MA 02199-7610  
(617) 342-4070  
lkraus@foley.com

Michael P. Matthews (*pro hac vice*)  
FOLEY & LARDNER LLP  
100 N. Tampa Street, Suite 2700  
Tampa, Florida 33602-5810  
(813) 225-4131  
mmatthews@foley.com

Rachel E. Kramer  
FOLEY & LARDNER LLP  
90 Park Avenue  
New York, New York 10016  
(212) 338-3545  
rkramer@foley.com

*Attorneys for Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A.*

Michael P. Matthews (*pro hac vice*)  
FOLEY & LARDNER LLP  
100 N. Tampa Street, Suite 2700  
Tampa, Florida 33602-5810  
(813) 225-4131  
mmatthews@foley.com

Lawrence M. Kraus (*pro hac vice*)  
FOLEY & LARDNER LLP  
111 Huntington Avenue, Suite 2500  
Boston, MA 02199-7610  
(617) 342-4070  
lkraus@foley.com

Rachel E. Kramer  
FOLEY & LARDNER LLP  
90 Park Avenue  
New York, New York 10016  
(212) 338-3545  
rkramer@foley.com

*Attorneys for Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A.*

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA ex rel. DON  
HANKS, et al.

Plaintiffs,

-against-

U.S. ONCOLOGY SPECIALTY, LLP et al.,

Defendants.

No. 08-cv-3096-SJ-RML

Hon. Sterling Johnson, Jr.

**DECLARATION OF  
RACHEL KRAMER**

RACHEL KRAMER declares as follows under penalty of perjury:

1. I am an attorney at Foley & Lardner LLP, counsel for defendants Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A. (“Defendants”). I am familiar with the facts and circumstances set forth herein. I make this declaration in support of Defendants’ motion to dismiss the Fifth Amended Complaint and to place certain documents before the Court.

2. True and correct copies of the following documents are attached hereto:

- |                  |  |
|------------------|--|
| <b>Exhibit A</b> | The Complaint in <i>Citizens for Consumer Justice v. Abbott Labs., Inc.</i> , No. 01-cv-12257 (D. Mass. filed Dec. 19, 2001)   |
| <b>Exhibit B</b> | The Complaint in <i>County of Suffolk v. Abbott Labs., Inc.</i> , No. 03-cv-00229 (E.D.N.Y. filed Jan. 14, 2003)   |
| <b>Exhibit C</b> | The Complaint in <i>County of Westchester v. Abbott Labs., Inc.</i> , No. 03-cv-06178 (S.D.N.Y. filed Aug. 18, 2003) <sup>1</sup>  |
| <b>Exhibit D</b> | Dep’t of Health & Human Services, Office of the Inspector General, <i>Audit of Amgen USA, Inc.’s Second Quarter 2005 Average Sales Price Calculation for Aranesp</i> (Jul. 2007) |
| <b>Exhibit E</b> | The Complaint in <i>Ortho Biotech Prods., L.P. v. Amgen Inc.</i> , No. 05-cv-04850 (D.N.J. filed Oct. 11, 2005)  |
| <b>Exhibit F</b> | The Complaint in <i>Sheet Metal Workers Nat’l Health Fund v. Amgen, Inc.</i> , No. 07-cv-5295 (D.N.J. filed Nov. 2, 2007)  |
| <b>Exhibit G</b> | Alex Berenson and Andrew Pollack, “Doctors Reap Millions for Anemia Drugs,” <i>N.Y. Times</i> (May 9, 2007)  |

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<sup>1</sup> Defendants have so far been able to obtain only a partial copy of this complaint.

3. Plaintiffs in the following actions alleged that Amgen manipulated Average Wholesale Price through the use of discounts, rebates or other price incentives:

<b>Case Name/Plaintiff</b>	<b>Filing Date</b>	<b>Case #</b>	<b>Court</b>
Average Wholesale Price Multidistrict Litigation	10/01	01-CV-12257-PBS (MDL 1456)	U.S. District Court, District of Massachusetts
State of Montana	2/25/02	02-CV-09-H-DWM	U.S. District Court, District of Montana
State of Nevada	3/8/02	CV-N-02-0202	U.S. District Court, District of Nevada
Commonwealth of Kentucky	9/15/03	03-CI-1135	Kentucky Circuit Court, Franklin County
Commonwealth of Pennsylvania	3/10/04	212 M.D. 2004	Commonwealth Ct. of Pennsylvania
State of Wisconsin	6/3/04	04-CV-1709	Wisconsin Circuit Court, Dane County
State of Alabama	1/26/05	CV-05-219	Alabama Circuit Court, Montgomery County
State of Illinois	2/7/05	05-CH-02474	Illinois Circuit Court, Cook County
State of Arizona	12/6/05	06-CV-11069-PBS (D. Mass)	Arizona Superior Court, Maricopa County (removed and transferred to U.S. District Court, District of Massachusetts multidistrict litigation)
Oswego County, New York	5/8/06	0697/2006	New York Supreme Court, Oswego County
State of Mississippi	10/5/06	G2005-2021	Chancery Ct of Hinds County, First Jud District
State of Alaska	10/6/06	34N-06-12026 CI	Alaska Superior Court, 3d Judicial Circuit, Anchorage
State of Iowa	11/07	07-CV-0461-JAJ	U.S. District Court, Southern District of Iowa
State of Kansas	11/3/08	08-CV-2191	District Ct, Wyandotte County
Erie County, New York	11/17/08	2439/2005	New York Supreme Court, Erie County
State of Louisiana	11/3/10	AWP-01-01126	State of Louisiana, Parish of East Baton Rouge, 19 <sup>th</sup> Judicial District

I declare under penalty of perjury that the foregoing is true and correct.

Dated: New York, New York  
August 1, 2014

s /Rachel E. Kramer  
Rachel E. Kramer



# EXHIBIT A

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

PM 10  
IN COURT HOUSE

Dec 18 4 00 PM '01

CITIZENS FOR CONSUMER JUSTICE,  
COLORADO PROGRESSIVE COALITION,  
CONGRESS OF CALIFORNIA SENIORS,  
FLORIDA ALLIANCE FOR RETIRED  
AMERICANS, HEALTH CARE FOR ALL, INC.,  
MASSACHUSETTS SENIOR ACTION COUNCIL,  
MASSPIRG, MINNESOTA SENIOR  
FEDERATION, NEW JERSEY CITIZEN ACTION,  
NEW YORK STATE WIDE SENIOR ACTION  
COUNCIL, PENNSYLVANIA ALLIANCE FOR  
RETIRED AMERICANS, VERMONT PUBLIC  
INTEREST RESEARCH GROUP, WEST  
VIRGINIA CITIZEN ACTION, and WISCONSIN  
CITIZEN ACTION,

Plaintiffs,

v.

ABBOTT LABORATORIES, INC., ALLERGAN  
WORLDWIDE, ALPHA THERAPEUTIC CORP.,  
AMERICAN BIOSCIENCE, INC., AMERICAN  
HOME PRODUCTS, AMGEN INC.,  
ASTRAZENECA US, AVENTIS PHARMA,  
BAYER AG, BAXTER INTERNATIONAL, INC.,  
BRISTOL-MYERS SQUIBB CO., CHIRON,  
FUGISAWA HEALTHCARE, INC.,  
GLAXOSMITHKLINE, PLC, GENSLA SICOR  
PHARMACEUTICALS, INC. GLAXO  
WELLCOME, INC., GLAXO WELLCOME, PLC,  
IMMUNEX CORP., ICN PHARMACEUTICALS,  
INC., HOESCHT MARION ROUSSEL, INC., ELI  
LILLY AND COMPANY, ONCOLOGY  
THERAPEUTICS NETWORK CORP.,  
PHARMACIA CORP., SCHERING-PLOUGH,  
CORP., SICOR, INC., SMITHKLINE BEECHAM  
CORPORATION, TAKEDA CHEMICAL  
INDUSTRIES LTD., TAP PHARMACEUTICAL  
PRODUCTS, INC., AND JOHN DOES 1 - 200,

Defendants.

) Case No.

) CLASS ACTION COMPLAINT

) Jury Trial Demanded

**01-12257 PBS**

RECEIPT # 35967  
AMOUNT \$ 150.00  
SUMMONS FEE. N  
LOCAL FEE 0.00  
WARRANT FEE 0.00  
MCF FEE 0.00  
AO 120 GR 121 ES  
BY DPTY CLK ES  
DATE 12/19/01

## COMPLAINT

Plaintiffs, on behalf of themselves and all others similarly situated, demanding a trial by jury, upon information and belief, except for information paragraphs five through sixteen which are based on personal knowledge, complain as follows:

### I.

#### INTRODUCTION

This is a class action brought under the § 16 of the Clayton Act, the Sherman Act, 15 U.S.C. § 1 and § 2, and the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §1961 *et seq.*, by Plaintiffs Citizens for Consumer Justice, Colorado Progressive Coalition, Congress of California Seniors, Florida Alliance For Retired Americans, Health Care for All, Inc., Massachusetts Senior Action Council, MassPIRG, Minnesota Senior Federation, New York StateWide Senior Action Council, Pennsylvania Alliance for Retired Americans, Vermont Public Interest Research Group, West Virginia Citizen Action, and Wisconsin Citizen Action (Plaintiffs) seeking relief on behalf of themselves and as representatives of the class which is defined herein.

1. The fraudulent scheme devised and initiated by defendants and implemented by their co-conspirators was effectuated by: (i) overstating the average wholesale price (AWP) for Medicare Covered Drugs, the basis for the determination of the Medicare reimbursement rate and the co-payment amount; (ii) promoting the sale of Medicare Covered Drugs through health care providers by selling the Covered Drugs to them at a price substantially less than the health care providers charged Medicare and Medicare Beneficiaries; and (iii) encouraging health care providers to claim Medicare reimbursement for free samples. As a result, the Defendants

developed, managed and maintained a regular and consistent scheme that resulted in billions of dollars of losses to Medicare and Medicare beneficiaries.

## II. JURISDICTION AND VENUE

2. Plaintiff brings this class action pursuant to § 16 of the Clayton Act, 15 U.S.C. § 26, to prevent Defendants Abbott Laboratories, Inc., Allergan Worldwide, Alpha Therapeutic Corp., American Bioscience, Inc., American Home Products Corporation, Amgen Inc., AstraZeneca US, Aventis Pharma, Bayer AG, Baxter International, Inc., Bristol-Myers Squibb Co., Chiron, Fugisawa Healthcare, Inc., GlaxoSmithKline, PLC, Gensia Sicor Pharmaceuticals, Inc. Glaxo Wellcome, Inc., Glaxo Wellcome, PLC, Immunex Corp., ICN Pharmaceuticals, Inc., Hoescht Marion Roussel, Inc., Eli Lilly and Company, Oncology Therapeutics Network Corp., Pharmacia Corp., Schering-Plough, Corp., Sicor, Inc., Smithkline Beecham Corporation, Takeda Chemical Industries, LTD, TAP Pharmaceutical Products, Inc., and JOHN DOES 1 – 200, from continuing to engage in exclusionary, monopolistic anticompetitive conduct in violation of §1 and § 2 of the Sherman Act that has harmed and continues to harm Plaintiffs and the Class.

3. This Court has subject matter jurisdiction over this matter pursuant to the Racketeer Influenced and Corrupt Organizations Act (RICO), 28 U.S.C. § 1331, and the Sherman Act, 15 U.S.C. § 26. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

4. The Court has jurisdiction to fashion equitable relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201.

Venue is proper within this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c) because defendants do business in this District, certain acts giving rise to the claims

asserted in this Complaint occurred within this District; and Plaintiffs or members of the Class sustained injury within this District as a result of Defendants' illegal actions.

### **III.** **PARTIES**

5. Plaintiff Citizens for Consumer Justice ("CCJ") is Pennsylvania's leading nonprofit umbrella organization for the promotion of affordable, quality health care. It is located at Architects Building, 117 South 17th Street, Ste. 311, Philadelphia, Pennsylvania. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CCJ has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

6. Plaintiff Colorado Progressive Coalition ("CPC") is a statewide nonprofit, multiracial network of groups and individuals united for racial and economic justice since 1996. It is located at 1420 Ogden Street, 1st Floor, Denver, Colorado. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CPC has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

7. Plaintiff Congress of California Seniors ("CCS") is a nonprofit organization representing over 650,000 Californian senior citizens and their families. It is located at 1228 N Street, Suite 29, Sacramento, California. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CCS has standing to

pursue this action under Federal Rule of Civil Procedure 17(b)(1).

8. Plaintiff Florida Alliance for Retired Americans ("FLARA") is a nonprofit umbrella organization formed in 1963 representing over 80 groups of retired Floridians with a cumulative membership of over 80,000 individuals. It is located at 12773 West Forest Hill Blvd., Ste. 1213, Wellington, Florida. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, FLARA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

9. Plaintiff Health Care For All, Inc. ("HCA") is a non-profit organization devoted to making health care a right of all people. It is located at 30 Winter Street, 10th Floor, Boston, Massachusetts. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, HCA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

10. Plaintiff Massachusetts Senior Action Council ("MSAC") is a nonprofit advocacy group for senior issues and especially champions health care issues. It has 3,000 individual members and over 60 affiliate organizations. It is located at 565 Warren Street, Dorchester, Massachusetts. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, ("MSAC") has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

11. Plaintiff MassPIRG is Massachusetts' largest consumer advocacy group. It is located at 29 Temple Place, Boston, Massachusetts. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MassPIRG has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

12. Plaintiff Minnesota Senior Federation ("MSF") is a statewide, nonprofit and nonpartisan organization with 25,000 active members and 400 affiliated organizations, representing 100,000 individuals in all 87 counties. It is located at 555 Park St., Ste 110, St. Paul, Minnesota. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MSF has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

13. Plaintiff New Jersey Citizen Action ("NJCA") is the state's largest independent citizen watchdog. It is located at 85 Raritan Ave., #100, Highland Park, New Jersey. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, NJCA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

14. Plaintiff New York StateWide Senior Action Council ("StateWide") is a grassroots membership organization made up of individual senior citizens and senior citizen clubs from all parts of New York State. It is located at 275 State Street, Albany, New York. During the class period, Plaintiff's members purchased prescription pharmaceuticals

manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, StateWide has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

15. Plaintiff Pennsylvania Alliance for Retired Americans ("PARA") is a nonprofit, advocacy group committed to promoting affordable healthcare. It is located at 2116 Chestnut St., Philadelphia, Pennsylvania. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, PARA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

16. Plaintiff Vermont Public Interest Research Group ("VPIRG") has been Vermont's leading watchdog and advocacy group since 1972. It is located at 141 Main Street, Ste 6, Montpelier, Vermont. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, VPIRG has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

17. Plaintiff West Virginia Citizen Action ("WVCA") is a nonprofit organization devoted to increase the voice of the average citizen in public affairs with an emphasis on health care reform. It is located at 1500 Dixie Street, Charlestown, West Virginia. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, WVCA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).



18. Plaintiff Wisconsin Citizen Action ("WCA") is the state's premiere public interest organization with 53,000 individual members and 250 affiliate organizations. It is located at 1202 Williamson St., Ste B, Madison, Wisconsin. During the class period, Plaintiff's members purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, WCA has standing to pursue this action under Federal Rule of Civil Procedure 17(b)(1).

19. Defendant Abbott Laboratories, Inc. ("Abbott") is a corporation organized and existing under the laws of the state of California. Abbott, one of the world's largest pharmaceutical companies, is in the business of manufacturing prescription medications, including Calcijex® (treatment for kidney failure and rickets) and Methapred® (a corticosteroid), for clinical distribution by Medicare providers nationwide. Abbott's revenues for the first half of 2001 were over \$7.6 billion.

20. Defendant Allergan, Inc. is a corporation organized and existing under the laws of the state of California. It is headquartered at 2525 Dupont Drive, Irvine, California. Allergan is in the business of providing eye care and specialty pharmaceutical products, including Genoptic®, for clinical distribution by Medicare providers nationwide.

21. Defendant Alpha Therapeutic Corporation (Alpha) is a corporation headquartered at 555 Valley Blvd., Los Angeles, California. Alpha is a subsidiary of Mitsubishi Pharma Corporation operating under California law. Alpha is in the business of providing home infusion products and services for clinical distribution by Medicare providers nationwide.

22. Defendant American Bioscience, Inc. (ABI) is a corporation headquartered in Santa Monica, California. ABI is a subsidiary of IVEX Corp. and Bristol-Myers Squibb, Co.,

existing and operating under California law. ABI is in the business of manufacturing and prescription drugs, including chemotherapy drugs, for clinical distribution by Medicare providers nationwide.

23. Defendant American Home Products Corporation ("AHP") is the parent company of Wyeth Worldwide. It is organized and exists under the laws of the state of New Jersey. American Home Products is one of the largest pharmaceutical and health care product companies in the world. Its annual sales in 2000 exceeded \$13.3 billion. Through its subsidiaries, AHP manufactures and distributes prescription drugs, including Ativan® (convulsive disorder medication), for clinical distribution by Medicare providers nationwide.

24. Defendant Amgen Inc. is a corporation organized and existing under the laws of the state of California. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals, including Epogen/Procrit® (for treatment of anemia) and Neupogen® (bone marrow transplant infection prevention), for clinical distribution by Medicare providers nationwide. In 2000, Amgen's revenues exceeded \$3.6 billion.

25. Defendant AstraZeneca US is a corporation organized and existing under the laws of the state of Delaware. AstraZeneca is in the business of manufacturing and distributing prescription pharmaceuticals, including Zoladex®, for clinical distribution by Medicare providers nationwide.

26. Defendant Aventis Pharma ("Aventis") is a corporation organized and existing under the laws of the state of New Jersey and operating in more than 120 countries in the world. Aventis is in the business of manufacturing and distributing prescription pharmaceuticals, including Pentacarinat® (pneumonia treatment), for clinical distribution by Medicare providers

nationwide. In 1999, Aventis's pro forma sales for its pharmaceuticals were \$3.3 billion.

27. Defendant Bayer AG is a corporation organized and existing under the laws of the Federal Republic of Germany, and maintains its principal place of business at 5090 Leverkusen, Bayerwerk, Federal Republic of Germany. Bayer AG is the parent company of Bayer Corporation, the subsidiary in the United States that sells and markets Medicare covered prescription drugs to clinical outsourcers. In 1999, Bayer AG derived approximately 30% of its \$30.6 billion of worldwide revenues from sales in the United States.

28. Defendant Baxter International Inc. ("Baxter") is a corporation organized and existing under the laws of Illinois. It maintains its principal place of business at One Baxter Parkway, Deerfield, Illinois. Baxter manufactures and distributes, Gammagard®, among other prescription drugs, to clinical outsourcers. Baxter's annual sales from January 1, 2000 through December 31, 2000 were \$6,896,000,000.

29. Defendant Bristol-Myers Squibb Co. ("Bristol-Myers") is a corporation organized in Delaware with a principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers manufactures and distributes prescription drugs, including Blenoxane® and Taxol® and other injectible cancer treatment drugs, that are clinically distributed by Medicare providers nationwide. Bristol-Myers' sales for the year 2000 were more than \$21 billion worldwide.

30. Defendant Chiron is a corporation organized and existing under the laws of the state of California. Chiron is in the business of manufacturing pharmaceuticals, including Depocyt® (anticancer drug), among other prescription drugs, to Medicare clinical outsourcers. Revenues for 2000 were \$972 million.

31. Defendant Fujisawa Healthcare, Inc. is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business located at Parkway North Center, Three Parkway North, Deerfield, Illinois. Fujisawa Healthcare, Inc. ("Fugisawa") is a subsidiary of Fujisawa Pharmaceutical Co., Ltd, headquartered in Osaka, Japan. Fugisawa develops and manufactures prescription drugs, including the immunosuppressant Prograf® (used in liver and kidney transplants) and Pentam® (used for treatment of pneumonia associated with AIDS), clinically distributed by Medicare providers nationwide.

32. Defendant GensiaSicor Pharmaceuticals, Inc. ("GSP") is a corporation organized and existing under the laws of the state of Delaware with a principal place of business located in Irvine, California. GSP is a wholly-owned subsidiary of SICOR, Inc. GSP manufactures prescription drugs for clinical distribution by Medicare providers nationwide.

33. Defendant GlaxoSmithKline PLC ("GSK") is a public limited company incorporated under the laws of England and Wales with corporate headquarters at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, United Kingdom UB6 0NN. GSK's operational headquarters are located at One Franklin Plaza, Philadelphia, Pennsylvania. GSK manufactures prescription drugs, including Zovirax® and other cancer and HIV drugs, clinically distributed by Medicare providers nationwide. GSK's annual pharmaceutical sales for the year 2000 were more than \$23.5 billion. Every second, more than 30 doses of vaccines are distributed by GSK.

34. Defendant Glaxo Wellcome PLC ("GW") was a public limited company incorporated under the laws of England and Wales, with corporate headquarters at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, United Kingdom UB6 0NN prior to

its merger with Defendant SmithKline Beecham PLC. GW manufactured prescription drugs including Ventolin® and Volmax® used for treating breathing disorders for clinical distribution by Medicare providers throughout the United States. In 1999, GW's sales totaled \$13.75 billion.

35. Defendant Glaxo Wellcome, Inc. (GWI) is a wholly-owned U.S. subsidiary of GlaxoSmithKline PLC organized and existing under the laws of the state of North Carolina. Its principal place of business is located at 5 Moore Drive, Research Triangle Park, North Carolina. GWI manufactures prescription drugs, including Zofran® (treats chemotherapy induced nausea), for clinical distribution by Medicare providers nationwide.

36. Defendant Hoechst Marion Roussel, Inc. ("HMR") is a wholly-owned subsidiary of Aventis S.A. (formerly Hoechst AG). HMR is a corporation organized and existing under the laws of the State of Delaware, and has its headquarters located at 10236 Marion Park Drive, Kansas City, Missouri. HMR develops and manufactures prescription drugs including Lasix® (high blood pressure treatment) for clinical distribution by Medicare providers nationwide.

37. Defendant ICN Pharmaceuticals, Inc. (ICN) is a corporation organized and existing under the laws of California. ICN is in the business of manufacturing prescription drugs, including Efudex® (precancerous skin disorder treatment) for clinical distribution by Medicare providers nationwide. ICN's revenues for the first quarter of 2001 were \$167 million.

38. Defendant Immunex Corporation is a corporation organized and existing under the laws of the state of Washington. Its principal place of business is located at 51 University Street, Seattle, Washington. Immunex manufactures immune system disorder and cancer treatment prescription drugs, including Novantrone® for clinical distribution by Medicare providers nationwide. Immunex's total revenues for 1999 were \$542 million.

39. Defendant Eli Lilly and Company (“Lilly”) is a corporation organized and existing under the laws of Indiana. Lilly is in the business of manufacturing prescription drugs, such as Nebcin® (for bacterial eye infection treatment), Vancocin® (bacterial infection treatment), and Oncovin® (for the treatment of some cancerous conditions) for clinical distribution by Medicare providers nationwide.

40. Defendant Oncology Therapeutics Network Corporation (“OTN”) is a wholly owned subsidiary of Bristol-Myers Squibb organized and existing under the laws of Delaware with its principal place of business in South San Francisco, California. OTN offers health care services to oncology practices. OTN’s revenues for the year 2000 exceeded \$1 billion. OTN manufactures prescription drugs for clinical distribution by Medicare providers nationwide.

41. Defendant Pharmacia Corp. is a corporation organized and existing under the laws of the state of New Jersey. Pharmacia’s corporate headquarters are located at 100 Route 206 North, Peapack, New Jersey. Pharmacia manufactures prescription drugs, including HIV and cancer treatment drugs (Amikin®, Neosar®, Toposar®, and Andrucil®), for clinical distribution by Medicare and Medicaid providers nationwide. Sales for the colorectal treatment drug, Camptosar®, and the breast cancer treatment drug, Ellence®, were \$441 million for the year 2000.

42. Defendant Schering-Plough, Corp. is a corporation organized and existing under the laws of the state of New Jersey. Its headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough manufactures prescription drugs, including Garamycin® (eye infection treatment), for distribution by Medicare providers nationwide.

43. Defendant SICOR, Inc. is a Delaware corporation organized and existing under the laws of California. Its principal place of business is located at 19 Hughes, Irvine, California. SICOR manufactures difficult-to-manufacture injectable pharmaceutical products for distribution by Medicare providers nationwide.

44. Defendant SmithKline Beecham PLC ("SKB") was a public limited company incorporated under the laws of England and Wales with corporate headquarters at New Horizons Court, Brentford, Middlesex, United Kingdom TW8 9BD. Prior to its merger with GW (to form GlaxoSmithKline PLC), SKB manufactured prescription drugs for clinical distribution by Medicare providers nationwide. SKB's total sales during 1999 were \$8.49 billion.

45. Defendant Smithkline Beecham Corporation ("SKBC") is a corporation organized and existing under the laws of the state of Pennsylvania. It is a wholly-owned subsidiary of GlaxoSmithKline PLC with a principle place of business located at One Franklin Plaza, Philadelphia, Pennsylvania. SKBC manufactures prescription drugs for clinical distribution by Medicare providers nationwide.

46. Defendant Takeda Chemical Industries LTD ("Takeda") is headquarter in Osaka, Japan with U.S. headquarters in Lincolnshire, Illinois. Takeda is one of the world's largest pharmaceutical manufacturers. Its 1999 net sales exceeded \$8.7 billion. Takeda develops and manufactures prescription drugs for clinical distribution by Medicare providers throughout the United States.

47. Defendant TAP Pharmaceutical Products, Inc. (TAP) is a corporation organized and existing under the laws of the state of Illinois. Its principal place of business is 675 Northfield Drive, Lake Forest, Illinois. TAP resulted from a merger between two of the world's

largest health care companies, Takeda Chemical Industries, Ltd. of Japan and Abbott Laboratories based in the United States. TAP manufactures prescription drugs for clinical distribution by Medicare providers nationwide.

48. The acts charged in this Complaint as having been done by the Defendants were authorized, ordered, or done by its officers, agents, employees, or representatives while actively engaged in the management of the Defendants' business or affairs.

#### **IV.** **CO-CONSPIRATORS AND DOE DEFENDANTS**

49. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, presently unknown to Plaintiffs and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted, or participated with Defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by Plaintiff and the other class members.

50. DOES 1-100 are corporations, companies, partnerships, or other business entities that participated in the illegal course of conduct that is the subject of this action as alleged herein.

51. DOES 101-125 are residents of the state of Massachusetts and are officers, employees, or agents of the defendants and/or entities owned or controlled by the defendants. DOES 101-125 participated in the illegal course of conduct that is the subject of this action as alleged herein.

52. DOES 126-150 are residents of states other than the state of Massachusetts and are officers, employees, or agents of the defendants and/or entities owned or controlled by the



defendants. DOES 126-150 participated in the illegal course of conduct that is the subject of this action as alleged herein.

53. DOES 151-200 are residents of countries other than the United States and are officers, employees, or agents of the defendants and/or entities owned or controlled by the defendants. DOES 151-200 participated in the illegal course of conduct that is the subject of this action as alleged herein.

54. Except as described herein, plaintiffs are, as yet, ignorant of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-200 inclusive and, therefore, sues these defendants by such fictitious names. Plaintiffs will amend this Complaint to allege the true names and capacities of the Doe Defendants when ascertained.

55. In addition, defendants unknown at this time may include independent physicians and other medical providers who prescribed Covered Drugs and engaged in fraudulent billing practices, as well as various other persons, partnerships, sole proprietors, firms, corporations and individuals that may have participated as co-conspirators with defendants in the offenses alleged in this Complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.

#### **IV. FACTS**

##### **A. The Medicare Insurance Program**

56. In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act") to pay for the cost of certain medical services and care. The Act was passed for the specific purpose of providing a coordinated and comprehensive approach to federal health insurance and medical

care for the aged and disabled. The Act and its associated programs, usually called “Medicare,” is codified at 42 U.S.C. §1395, *et seq*

57. As a general rule, the Medicare Program does not pay for the cost of most prescription pharmaceuticals, such as drugs which a Medicare beneficiary self-administers by swallowing in liquid or pill form when originally enacted into law, pharmaceuticals played a less prominent role than the widespread reliance upon pharmaceuticals in health administration today. Nevertheless, Medicare Part B, allows for payment of certain “Covered Drugs.” Covered Drugs include only the following: (i) those that must be administered by a health care provider; (ii) drugs needed to facilitate the use of covered durable medical equipment; (iii) certain immunizations; and (iv) some self-administered drugs usually relating to cancer or immunosuppressant therapy.

58. Congress crafted Medicare Part B to provide supplementary medical insurance for those aged and disabled individuals who elect to enroll under the program.

59. The U.S. Department of Health and Human Services (“HHS”) is responsible for the funding, administration and supervision of the Medicare program. Congress specifically created a program to administer Medicare through contracts with organizations that already served as payers of health care services. In doing so, it chose to pay on the basis of the contractors’ allowable costs so the contractors would neither be penalized nor would they unduly profit for administering the program. A division of the HHS, the Health Care Financing Administration (“HCFA”), is responsible for ensuring that contractors administer the program efficiently and accurately.

60. HCFA relies on the contractors themselves to certify that their controls over the accuracy and security of their payment and data systems are sound.

61. The provider's nomination provision in the Medicare Act allows the professional associations of hospitals and certain other institutional providers to choose claims processing intermediaries on behalf of their members. Accordingly, HCFA does not have authority to freely choose the companies with which it may contract as Medicare intermediaries.

62. The allowed amount to be paid for a drug under Medicare is determined under the payment methodology set forth in 42 C.F.R. § 405.517, which was published in the Federal Register on November 25, 1991 and became effective on or about January 1, 1992 as amended at 63 FR 58849.

63. Under 42 C.F.R. § 405.517, drugs and biologicals not paid on a cost or prospective basis are paid based on the lower of the billed charge or 95 percent of the AWP as posted in sources such as the Red Book or Medispan.

64. Prior to January 1, 1998, the amount Medicare would allow health care providers to charge for Covered Drugs under Medicare Part B was the lower of either: (i) the "estimated acquisition cost" or (ii) ninety-five percent (95%) of the "national average wholesale price" (AWP) for the particular drug. At that time, the estimated acquisition cost for a drug could be determined by the Medicare program "based on surveys of the actual invoice prices paid for the drug." In determining the estimated acquisition cost, the Medicare Program considered "factors such as inventory, waste and spoilage."

65. Since January 1, 1998, the AWP has been calculated as follows: (1) for a single source drug or biological, the AWP equals the AWP of the single product; (2) for a multi-source

drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP; and (3) after determining the AWP, the allowance limit is calculated by multiplying the AWP by 0.95.

66. Medicare relies on the AWP published in pharmaceutical industry publications, such as the Red Book and Medispan, to ascertain the Medicare reimbursement amount. Payment allowances for drugs and biologicals are described in HHS Program Memorandum AB-99-63 which states that drugs and biologicals are to be reimbursed by the Medicare Program based on the lower of the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication sources such as the Red Book or Medispan.

67. Medicare Part B reimburses medical providers 80% of the allowable amount. The Medicare beneficiary, or his or her insurer, pays the additional 20% (usually called the “co-payment”). In addition, beneficiaries under Part B are required to pay an annual deductible amount before Part B coverage is available.

68. Ostensibly the industry publications provide objectively verifiable AWP figures for Medicare Covered Drugs. The Department of Justice (“DOJ”), the National Association of Medicaid Fraud Control Units (“Medicaid Fraud Units”) and Group Purchasing Organizations (“GPOs”) have compiled data from wholesalers’ catalogs on 400 national drug codes representing about 50 different chemical compounds. The wholesaler catalogs, listing wholesale prices, are, according to the DOJ, a more accurate representation of the true wholesale cost than prices published by the Defendants in either the Red Book or Medispan.

69. The wholesale catalog prices reveal that the Defendants have grossly inflated the true average wholesale price for Medicare Covered Drugs. For instance, the catalog wholesale

price for one drug was \$22. The same drug listed for \$73 in the Red Book. GPOs offered the same drug at \$15.

70. The published AWP's currently used by Medicare-contracted carriers to determine reimbursement bear little or no resemblance to actual wholesale prices available to the health care providers who bill for these drugs.

71. Because the Defendants directly control the AWP listed in the industry publications and relied upon by the Medicare Program for reimbursement rates, the Defendants regularly and unjustifiably raised the AWP in order to capture, control and eviscerate the relevant market.

72. As a direct and proximate result of defendants' pattern of artificially and fraudulently inflating the AWP for Covered Drugs above the average wholesale price actually reflective of the relevant market, Plaintiffs and members of the Class substantially overpaid, in whole or in part, for the drugs and biologicals covered under Medicare Part B.

B. The Ongoing Government Investigation

73. In early 1999, the Congressional Committee on Commerce ("Commerce Committee") began to investigate the prices Medicare pays for Covered Drugs. Over the course of the Investigation, the committee staff reviewed almost 100,000 pages of internal drug manufacturers' documents relating to pricing. In May 2000, the Commerce Committee stated that:

[its] investigative work has produced evidence indicating that some drug companies may be reporting artificially inflated reimbursement rates . . . and may be manipulating such prices in order to assist their sales and marketing efforts aimed at healthcare providers.

(Letter dated May 4, 2000 from the Chairman of the Commerce Committee to SmithKline Beecham.).

74. At least as early as 1997, the DOJ, the United States General Accounting Office (“GAO”), the Office of the Inspector General at HHS (“OIG”), and certain Congressional subcommittees began investigating the defendants and other pharmaceutical manufacturers for questionable practices regarding the industry’s calculation of the AWP and offering illegal incentives to health care providers.

75. In 1997, the OIG, comparing Medicare reimbursement in 1996 for twenty-two of defendants’ Plan B prescription drugs with the cost of acquiring the same drugs through sources other than the defendants and concluded that Medicare reimbursement, for these twenty-two drugs *alone*, exceeded the actual wholesale prices by \$447 million. Exhibit A.

76. In the same study, the OIG concluded that Medicare would have saved \$445 million on the same twenty-two drugs in 1995. Of these twenty-two drugs, the OIG found that Medicare had paid twice the AWP for about one-third of them. It also found no consistency between carriers in establishing and updating the AWP’s listed in the industry publications. Exhibit A.

77. In 1998, the OIG reviewed drug costs in the Department of Veteran Affairs (“VA”) as compared to Medicare costs for the same drugs. The OIG chose to focus on the 34 drugs that had each resulted in at least \$10 million in Medicare allowed charges in 1996. The review revealed that if Medicare had purchased these drugs at the same rates paid by the VA, Medicare and its beneficiaries would have saved \$1.03 *billion* in 1998 on these 34 drugs *alone*.

78. In 1999, the GAO, recognizing and recapping the various investigations, concluded that it was clear that Medicare was vulnerable to erroneous and fraudulent billing practices by healthcare providers.

79. The Chairman of the House Commerce Committee, Representative Tom Bliley, relying on the OIG's reports, in a letter to then Secretary of Health and Human Services, Donna Shalala, noted that "Medicare could have saved at least 40 percent of the current allowance for almost half the 22 drugs, and 93 percent for one particular drug, by limiting reimbursement to the available private sector prices for those drugs."

80. In Secretary Shalala's response, she proposed lowering the reimbursement rate to the health care provider's actual acquisition rate.

81. The DOJ accumulated price data from a number of wholesale drug catalogs and provided the data to First DataBank to compile for use by the pharmaceutical industry in calculating its AWP.

82. On May 21, 2000, as a result of the DOJ's investigation, HCFA announced plans for Medicare to use AWP's developed by Medicare.

83. In September 2000, HCFA authorized Medicare carriers to use the prices compiled by First DataBank in reimbursing Plan B claims.

84. In November 2000, HCFA rescinded the order to the carriers due to concerns raised by providers.

85. In December 2000, Congress passed legislation requiring the GAO to complete a more comprehensive study before permitting HCFA to put in place the lower reimbursement rates. The GAO published the study in September 2001.

86. After HCFA required its carriers to establish new reimbursable amounts, the OIG ran a study comparing the Medicare allowable amount for 24 drugs to the amount reimbursable under Medicaid and the VA. These drugs represented 79% (or \$3.1 billion) of the \$3.9 billion in total Medicare drugs for 1999.

87. OIG concluded that Medicare and Medicare beneficiaries would have saved \$1.6 billion in 1999 if they had paid the same price for the 24 drugs that the VA paid. Medicare reimbursement rates were fifteen to ninety-one percent greater than the prices paid by the VA.

88. The OIG's analysis of the AWP list lead to the conclusion that in the year 2000, Medicare had paid at least \$887 million more than the actual wholesale prices it had paid based on the pharmaceutical industry's listed average wholesale prices.

89. In September, 2001, the GAO reported to the Commerce Committee that Medicare had been paying much more than the health care providers' true acquisition costs. HHS's Centers for Medicare and Medicaid services confirmed the GAO's report, noting that Medicare's payments for drugs were substantially higher than the actual cost to those who administered the drugs. The GAO concluded that as a result of payments by Medicare based on the "AWP, a price that may be neither an average nor what wholesalers charge, Medicare has been paying much more than providers' likely acquisition costs."

90. On September 21, 2001, Thomas A. Scully, Administrator for HHS' Centers for Medicare and Medicaid Services testified before the Subcommittees on Health, and Oversight and Investigations of the Congressional Committee on Energy and Commerce, that the:

Numerous studies have indicated that the industry's reported wholesale prices, the data on which Medicare payments are based, are vastly higher than the amounts that drug manufacturers and wholesalers actually charge providers. That means Medicare



beneficiaries, through their premiums and cost sharing, and U.S. taxpayers are spending far more than the “average” price that we believe the law intended them to pay.

Scully also noted that Medicare now pays more than many other purchasers for the drugs Medicare covers due to the way drug manufacturers and wholesalers report their prices and due to Medicare’s payment policies.

B. Scope of Medicare Benefits

91. Congress created Medicare supplemental insurance coverage for some pharmaceuticals and services for aged and disabled individuals electing to enroll and financed the plan from premium funds paid by the enrollees and tax payer contributions.

92. Medicare Part B entitles enrollees to have payment for medical and other health services, including payment for Covered Drugs and biologicals.

93. Each enrollee incurring expenses for benefits and services covered under Medicare Part B is entitled to recover from the program, or have the program pay directly to the health care provider, 80 percent of the reasonable charges for the covered services.

94. Where a health care provider elects to accept payment directly from the program, it may not charge the individual enrollee more than 20 percent of the reasonable cost of the Covered Drug or biological. See 42 U.S.C. § § 1395(j) – 1395(w-4).

C. Defendants’ Fraudulent Marketing Scheme

95. As part of Defendants scheme to induce health care providers to prescribe the drugs they manufacture, Defendants grossly inflated the average wholesale price for Covered Drugs, sold the drugs to the providers at a far lower price, encouraged health care providers to fraudulently charge Medicare and Medicare Beneficiaries at the AWP amount and also

encouraged providers to bill for so-called “free” samples.

96. Relying on the artificially inflated prices that defendants intentionally posted in pharmaceutical industry publications, defendants charged the treating health care provider substantially less than the health care providers could charge under the AWP fee calculation. The higher the AWP and the lower the actual cost, the greater the “spread” and therefore, the greater the incentive to prescribe defendants’ Covered Drugs. Health care providers prescribing Covered Drugs thus generated large, unlawful profits at the expense of the Medicare Program, Medicare Co-Payers, and Third Party Payors, including Plaintiffs and the Class.

97. Defendants created this scheme in order to capture and manipulate a market. Defendants did so intentionally and with impunity because defendants knew Congress and the Medicare reimbursement system trusted them to accurately and justly compute the AWP relied on to calculate reimbursement for Covered Drugs.

98. The execution of this scheme of fraudulent incentives was an interstate endeavor intentionally carried out by defendants’ employees. Widespread, interstate cooperation of health care providers was also a necessary component of defendants’ fraudulent incentive scheme.

99. Defendants also have provided and/or arranged for many other financial inducements to stimulate sales of Covered Drugs at the expense of plaintiffs and the Class. Such inducements included volume discounts, rebates, off-invoice pricing, and free goods, including gifts of cash and other items of value directly to health care providers. The defendants used these incentives to increase the net profits for the prescribing doctor in order to capture, manipulate, and monopolize the relevant market.

D. Defendants' Use of the Mails and Wires in Furtherance of the Scheme

100. Defendants' illegal conduct and practice was carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfer of information and funds by mail and wire.

101. The nature and pervasiveness of defendants' fraudulent marketing scheme, orchestrated from defendants' corporate headquarters, necessarily required those defendant headquarters to communicate directly and frequently by United States mail and by facsimile over wire with the various local district managers overseeing the sales force and the numerous pharmaceutical sales representatives who, in turn, directly communicated with the prescribing doctors.

102. Defendants' conduct included mailing and transmitting via interstate wires numerous marketing and sales materials relating to Covered Drugs, Medicare reimbursement rates and profit margins to be earned by prescribing the drug. Defendants also used the mail and wires to set-out the AWP listings in industry publications, as well as to arrange illegal financial inducements discussed herein. Defendants also shipped free samples of the products that were used as inducements to physicians to induce them to prescribe Covered Drugs.

E. Effects of Defendants' Scheme on The Relevant Market and the Class

103. Defendants' illegal marketing scheme has substantially increased Covered Drugs market share and total sales figures.

104. A substantial portion of the grossly inflated revenues defendants derived from Medicare Beneficiaries through payment of the twenty percent co-payment, payment of the deductible, or when the beneficiary owned no insurance coverage, through complete payment of

the cost of the Covered Drug.

### **CLASS ACTION ALLEGATIONS**

105. Plaintiffs bring this Declaratory Judgment, antitrust class and RICO action pursuant to Rule 23 of the Federal Rules of Civil Procedure, subsections 23(a) and 23(b)(2) and/or (b)(3), on behalf of a class defined as follows:

All individuals or entities who paid any portion of the 20% co-payment and/or deductible amount for themselves or for their beneficiaries under Medicare Part B for Covered Drugs manufactured and/or distributed by defendants during the period 1993 through the present (class period).

106. Excluded from the Class are all defendants, their respective subsidiaries and affiliates, all governmental entities, and all judges and justices assigned to hear any portion of this case.

107. The members of the Class are so numerous (Medicare beneficiaries number over 40 million nationally) that joinder of all members is impracticable. Plaintiffs claims are typical of the claims of the Class Members. Defendants' illegal, anticompetitive and inequitable methods, acts and trade practices have targeted and affected all members of the Class in a similar manner, *i.e.*, they have been deprived of a competitive market to ensure accurate and fair drug pricing due to the deceitful practices of the Defendants.

108. Plaintiffs will fairly and adequately protect the interests of the Class. The interests of the plaintiffs coincide with, and are not antagonistic to those of, the Class. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex Class action litigation, including, for example, in the areas of mass tort, healthcare, consumer and antitrust class actions.

109. Questions of law and fact common to the Class include, but are not limited to:

- (a) Whether defendants engaged in a fraudulent scheme of improperly setting and/or adjusting the AWP for Covered Drugs;
- (b) Whether defendants artificially inflated the AWP for Covered Drugs in order to increase their market share, sales figures, and revenues;
- (c) Whether defendants prepared marketing and sales materials containing comparisons of the Red Book AWP for the Covered Drugs and the actual average wholesale price for these same drugs;
- (d) Whether defendants provided free samples of Covered Drugs to doctors and other health care professionals so as to induce them to prescribe Covered Drugs to their patients;
- (e) Whether defendants instructed doctors and other health care professionals to seek Medicare reimbursement and consumer co-payment for free samples of Covered Drugs;
- (f) Whether defendants encouraged doctors and other health care providers to prescribe defendants' Covered Drugs to patients in lieu of competing drugs;
- (g) Whether defendants engaged in a pattern and practice of selling Covered Drugs to health care providers at a price well-below the Red Book listed AWP that the health care providers could recoup from Medicare (the "spread" price) so as to induce them to prescribe Covered Drugs to their patients;
- (h) Whether defendants have monopolized and/or attempted to monopolize the relevant markets;
- (i) Whether defendants engaged in a pattern of racketeering activity as defined under RICO;
- (j) Whether defendants participated in the operation and management of the association-in-fact conspiracy.
- (k) Whether defendants received income derived from a pattern of racketeering activity and used or invested such income in the establishment and operation of the conspiracy;
- (l) Whether defendants used or invested the income derived from a pattern of

rackeering activity in the operation or management of the conspiracy;

- (m) Whether plaintiffs and members of the Class were injured within the meaning of §1964(c) of RICO as a direct and proximate result of defendants' investment or other use of illegally-obtained income into the conspiracy;
- (n) Whether the defendants' unlawful activities affected interstate commerce;
- (o) Whether defendants engaged in a pattern of racketeering activity intended to defraud the Class;
- (p) Whether plaintiffs and members of the Class were injured within the meaning of §1964(c) of RICO, as a direct and proximate result of defendants' racketeering activities and predicate acts consisting of a wrongful scheme intended to defraud plaintiffs and the Class;
- (q) Whether defendants' fraudulent scheme was carried out and furthered by the use of the United States mail and interstate wire services; and
- (r) Whether defendants are liable to plaintiffs and the Class for treble damages for conduct actionable under the civil provisions of the RICO statute.
- (s) Whether the alleged conduct herein constitutes a violation of § 1 of the Sherman Act;
- (t) Whether the alleged conduct herein constitutes a violation of § 2 of the Sherman Act;
- (u) Whether the alleged conduct herein has harmed plaintiffs and other members of the Class;
- (v) Whether injunctive relief is necessary to prohibit defendant from engaging in unlawful conduct in the future; and
- (w) Whether defendants violated state antitrust and deceptive trade practice statutes identified herein.

110. The above-identified common questions predominate over individual questions, if any, that may affect the Class.

111. Class action treatment is a superior method for the fair and efficient adjudication of the controversy because it permits large numbers of similarly situated persons to prosecute common claims in a single forum simultaneously, efficiently, cost effectively in a manner that would be impossible if each individual filed separate actions. Furthermore, prosecution of separate actions by individual Class members would create an inherent risk of inconsistent and varying adjudications, with the concomitant risk of establishing incompatible and conflicting standards of conduct for defendants.

112. Adjudications with respect to individual members of the Class could, as a practical matter, be dispositive of the interests of others not party to the adjudications or substantially impair or impede their ability to protect their interests.

#### **THE RELEVANT MARKET**

113. The sale of pharmaceuticals is a multi-billion dollar a year industry. Each Covered Drug constitutes a relevant product market.

114. The relevant geographic market is the United States.

115. Defendants possess the dominant and persistent market share for each Covered Drug in the United States.

#### **FRAUDULENT CONCEALMENT**

116. The running of any statute of limitations has been tolled by reason of defendants' fraudulent concealment. Defendants and their co-conspirators actively concealed their fraudulent scheme to grossly inflate the prices charged for Covered Drugs by reporting AWP's that bore no relationship to the actual market cost of the Covered Drugs.

117. Defendants throughout the period of their unlawful conduct, secretly and covertly met, discussed and agreed with each other and their co-conspirators to artificially elevate the price charged for Covered Drugs. Many, if not most, of those meetings, discussions and agreements took place, in whole or in part, in private. Plaintiffs and members of the Class were unaware of and could not through diligence have discovered these meetings and the unlawful conspiracy.

#### **IV.**

#### **COUNT I**

**(For Declaratory and Injunctive Relief Pursuant to 28 U.S.C. § § 2201 and 2202)**

118. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint and further allege against defendants, and each of them, as follows:

119. Defendants have engaged in fraudulent, anticompetitive and conspiratorial conduct undermining the benefits Congress intended Medicare recipients to enjoy.

120. Defendants have interfered with and/or deprived plaintiffs' and the Class members' of their statutory rights, privileges and entitlements.

121. By virtue of defendants' illegal conduct, defendants are obligated to remedy the harm they have caused plaintiffs.

#### **COUNT II**

**(Violation of § 1 of the Sherman Act, 15 U.S.C. § 1)**

122. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint, and further allege against defendants, and each of them, as follows:



123. Since 1993 and continuing into the present, the defendants have conspired to unreasonably restrain trade and commerce by manipulating the prices of Covered Drugs paid by Medicare and Medicare beneficiaries.

124. Defendants' combinations and conspiracy has resulted from concerted efforts by defendants to capture the Medicare Covered Drug market and fix, raise and maintain control over exorbitant prices and the relevant market.

125. As a direct and proximate result of defendants' illegal conduct as described above, plaintiffs and members of the Class paid grossly inflated prices for Covered Drugs.

126. As a direct and proximate result of defendants' illegal violation of the antitrust laws, defendants have threatened loss or caused real damage to plaintiffs and members of the Class. The prices charged by defendants for Covered Drugs are substantially greater than the prices Medicare beneficiaries would have paid absent the illegal conduct. As a result of defendants' conduct, Medicare beneficiaries continue to sustain substantial losses and damages to their business and property.

### **COUNT III**

#### **Violation of § 2 of the Sherman Act, 15 U.S.C. § 2)**

127. Plaintiffs, on behalf of themselves and all others similarly situated, reallege and incorporate herein by reference each of the allegations contained in the preceding paragraphs of this Complaint, and further allege against Defendants, and each of them, as follows:

128. Defendants conspired to monopolize, and successfully monopolized, the market and production of Medicare Plan B Covered Drugs. The incentives and inducements provided to health care providers and Defendants' resulting relevant market control are evidence of Defendants' monopoly and they are, therefore, a per se violation of § 2 of the Sherman Act and

are otherwise a violation of § 2 of the Sherman Act.

129. Defendants engaged in a vertical monopolization of the Medicare Covered Drug market in violation of § 2 of the Sherman Act under a rule of reason analysis.

130. As a direct and proximate result of the illegal conduct of defendants as described above, plaintiffs and members of the Class paid artificially inflated prices for Medicare Plan B Covered Drugs were deprived of the ability to purchase these drugs at the true average wholesale price. As a direct and proximate cause of defendants' illegal violation of the antitrust laws, defendants have threatened loss or damage to plaintiffs and members of the class. The prices charged by defendants for Medicare Plan B Covered drugs are substantially greater than the prices consumers would have paid absent the illegal conduct. As a result of defendants' conduct alleged herein, consumers continue to sustain substantial losses and damage to their business and property.

**COUNT IV**  
**(Violation of 18 U.S.C. §1962(c))**

131. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

132. Defendants are "persons" within the meaning of §1961(3) who conducted the affairs of both an enterprise and an association-in-fact enterprise affecting through a pattern of racketeering activity in violation of 18 U.S.C. §1962(c).

133. The enterprise at issue is an association-in-fact within the meaning of 18 U.S.C. §1961(4) because it consists of a group of persons associated together for the common purpose of selling, purchasing and providing Covered Drugs to the Class and earning profits from the provision of those services. The enterprise consists of the various and independent physicians

and other medical providers who prescribed Covered Drugs and engaged in fraudulent billing practices and the defendants, including their directors, employees, and agents who conspired with the medical providers to monopolize the relevant market. The defendants' enterprise is an on-going and continuing business organization consisting of both corporations and individuals associated for the common purposes of selling, purchasing, prescribing, and administering Covered Drugs to Plaintiffs and members of the Class and deriving profits from these activities that functions as a continuing unit.

134. The enterprise engages in and affects interstate commerce because it engages in the following activities across state boundaries: the sale and/or purchase of Covered Drugs, the transmission of sales and marketing literature, and the transmission and/or receipt of invoices and payments related to the use of Covered Drugs. In addition, the enterprise prescribes and/or administers Covered Drugs to thousands of Medicare beneficiaries throughout the United States.

135. Defendants have exerted control over the enterprise and have directly or indirectly conducted or participated in the conduct of the affairs of the enterprise, in the following ways:

- (i) Defendants have directly controlled the price at which physicians and other medical providers purchase Covered Drugs;
- (ii) Defendants have directly controlled the AWP reported in industry publications;
- (iii) Defendants have directly controlled the price at which physicians and other medical providers are reimbursed by the Medicare Program;
- (iv) Defendants have directly controlled the creation and distribution of marketing, sales, and other materials used to inform physicians and other medical providers nationwide of the profit potential of Covered Drugs;

- (v) Defendants have directly controlled the marketing and sales scheme to use the artificially and unlawfully inflate the Medicare reimbursement rate (and co-payment rate) to induce physicians and other medical providers to prescribe Covered Drugs to their patients;
- (vi) Defendants have directly controlled the use and distribution of free samples of Covered Drugs to physicians and other medical providers;
- (vii) Defendants have directly or indirectly counseled and induced physicians and other medical providers to unlawfully seek reimbursement from the Medicare Program for free samples;
- (viii) Each Defendant has relied upon its employees and agents to promote the fraudulent marketing schemes herein alleged through the mail, through the wires, and through direct contacts with physicians and other medical providers; and
- (ix) Each Defendant has controlled and participated in the conspiracy by using a fraudulent scheme to manufacture, market and sell Covered Drugs through the use of unlawful inducements to physicians and other medical providers.

136. Defendants have conducted and participated in the affairs of the conspiracy through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §1341, relating to mail fraud, and 18 U.S.C. §1343, relating to wire fraud. Defendants' pattern of racketeering likely involved hundreds, even thousands, of separate instances of use of the United States mail or the interstate wires in furtherance of their fraudulent and unlawful marketing scheme. Each of these fraudulent mailings and interstate wire transmissions separately constitutes a "racketeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively,

these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. §1961(5) in which the defendants intended to defraud plaintiffs and members of the Class.

137. Defendants' fraudulent and unlawful marketing scheme consisted first of deliberately overstating the AWP for Covered Drugs, creating a "spread" based on the inflated figure to induce physicians and other medical providers to prescribe Covered Drugs to their patients, thereby causing the Medicare Program to pay an artificially-inflated rate of reimbursement for Covered Drugs. Defendants' fraudulent and unlawful marketing scheme also consisted of providing free samples of Covered Drugs to physicians and other medical providers instructing these professionals to bill the Medicare Program for these free samples and providing other unlawful financial incentives, including kickbacks and bribes to induce use of Covered Drugs.

138. These schemes were calculated and intentionally crafted to ensure that Medicare and Medicare beneficiaries would overpay for Covered Drugs. In designing and implementing these fraudulent schemes, defendants were at all times cognizant of the fact that the entire Medicare Program and all patients for whom Covered Drugs are prescribed, rely upon the honesty of defendants in setting the AWP as crafted and disseminated by the defendants.

139. By intentionally and artificially inflating the AWP and by pervasively providing physicians and other medical providers with unlawful financial inducements to use Covered Drugs, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the United States mail or interstate wire transmission, defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

140. These racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive plaintiffs and members of the class. Each separate instance of a racketeering activity perpetrated by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including plaintiffs and members of the Class. Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Prescription Enterprise.

141. Defendants' violations and pattern of racketeering activity have directly and proximately caused plaintiffs and members of the Class to be injured in their property insofar as plaintiffs and members of the Class have paid millions of dollars in inflated reimbursements or other payments for Covered Drugs.

142. Plaintiffs and members of the Class have relied to their detriment on billing statements based on information reported directly or indirectly by Defendants sent through the United States mail. As a result of Defendants' fraudulent acts, the billing statements so distributed have resulted in unjust overpayment from Plaintiffs and members of the Class.

143. By virtue of these violations of 18 U.S.C. §1962(c), Defendants are jointly and severally liable to plaintiffs and members of the Class .

**COUNT V**  
**(For Violation of 18 U.S.C. §1962(a))**

144. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

145. Throughout the Class Period, defendants have violated the federal RICO statute by using and investing income that was derived from a pattern of racketeering activity as herein

discussed to acquire, establish and/or operate a variety of enterprises engaged in and affecting interstate commerce.

146. The enterprise is an association-in-fact within the meaning of 18 U.S.C. §1961(4) that were created and/or used as tools to effectuate defendants' pattern of racketeering activity. The defendants' enterprise, an ongoing organization functioning as a continuing unit, falls within the meaning of 18 U.S.C. §1961(4) insofar as it consists of a group of "persons" associated together for the common purposes of buying, selling, prescribing, and administering Covered Drugs to the Class and their individual participants and deriving profits from these activities.

147. Defendants engaged in a pattern of racketeering activity as set out herein.

148. Plaintiffs and members of the Class have been directly and proximately injured in their property by the defendants' use and investment of the racketeering income into the acquisition, establishment and operation of the defendants' enterprise. The injury to plaintiffs' and the Class members' business or property stemming from these violations has been realized in the form of millions of dollars in over-payments they expended for Covered Drugs.

149. The use and investment of racketeering income by the defendants directly and proximately injured the plaintiffs and members of the Class in a manner that was distinct from the injury caused by the pattern of racketeering activity described herein.

150. Plaintiffs and members of the Class relied, to their detriment, on the fraudulent billing statements sent to them through the United States mails.

151. By virtue of these violations of 18 U.S.C. §1962(a), defendants are jointly and severally liable to plaintiffs and members of the Class.

**COUNT VI**  
**(For Violation of 18 U.S.C. §1962(d))**

152. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further allege as follows.

153. Pursuant to 18 U.S.C. §1962(d), “[i]t shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b), or (c) of this section.”

154. Defendants violated §1962(d) by conspiring to violate 18 U.S.C. §1962(a) and (c).

155. Defendants together conspired and agreed to derive, and ultimately did derive, substantial income and proceeds from the above-described pattern of racketeering activity. Defendants further conspired and agreed to use or invest, and did use or invest, directly or indirectly, a significant portion of such income or proceeds in the operation or management of the enterprise, described above, in violation of 18 U.S.C. §1962(d) by conspiring to violate 18 U.S.C. §1962(a).

156. The use or investment of such monies directly and proximately injured plaintiffs and members of the Class, in a manner that was distinct from the injury caused by the pattern of racketeering activity described herein, because it enabled, furthered, and perpetuated the ongoing scheme of over-billing Medicare, Medicare beneficiaries and members of the Class for Covered Drugs.

157. Defendants also violated section 1962(d) by conspiring and agreeing to violate 18 U.S.C. §1962(c). The object of the conspiracy and agreement was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Defendants’ enterprise through a pattern of racketeering activity. Defendants’ pattern of racketeering activity directly and proximately caused plaintiffs and the Class to be injured in their business and property.



158. As a direct and proximate result of Defendants' direct and indirect acts in furtherance of violating 18 U.S.C. §1962(d) by conspiring to violate 18 U.S.C. § §1962(a) and (c), Plaintiffs and members of the Class were injured in their business or property.

**PRAYER FOR RELIEF**

**WHEREFORE**, plaintiffs and absent Class members pray judgment against the defendants and seek relief as may be allowed by law, including interest and costs of court as follows:

1. Under Count I, an entry by the Court adjudging the defendants conduct to be an illegal violation of plaintiffs' rights pursuant to the Social Security Act;
2. On all Counts, an award to plaintiffs and the Class of any and all other appropriate equitable relief;
3. On all Counts, an award of such other and further relief as may be just and proper under the circumstances.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand a jury trial on all issues so triable.

Date: December 19, 2008

By: Thomas M. Sobol / s  
Thomas M. Sobol (TMS 471770)  
Nicole Y. Brumsted (NYB 3557)  
**LIEFF CABRASER HEIMANN &  
BERNSTEIN, LLP**  
175 Federal Street, 7th Floor  
Boston, MA 02110  
Telephone: (617) 720-5000  
Facsimile: (617) 729-5015

Michael J. Flannery  
**CAREY & DANIS, LLC**  
676 North Michigan Avenue  
Suite 3110  
Chicago, IL 60611  
Telephone: (312) 649-0100  
Facsimile: (312) 649-0603

David J. Bershad  
J. Douglas Richards  
Michael M. Buchman  
**MILBERG WEISS BERSHAD HYNES &  
LERACH, LLP**  
One Pennsylvania Plaza New York, NY  
10119-0165  
Telephone: (212) 594-5300  
Facsimile: (212) 868-1229

Robert G. Eisler  
**LIEFF CABRASER HEIMANN &  
BERNSTEIN, LLP**  
780 Third Avenue, 48th Floor New York, NY  
10017-2024 Telephone: (212) 355-  
9500 Facsimile: (212) 355-9592

# **EXHIBIT B**

ORIGINAL

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

COUNTY OF SUFFOLK,

Plaintiff,

v.

ABBOTT LABORATORIES, INC., AG SCIENTIFIC  
INC., AGOURON PHARMACEUTICALS, INC.,  
AMGEN, INC., ASTRAZENECA US, BAYER AG,  
BERLEX LABORATORIES, INC., BIOGEN, INC.,  
BRISTOL-MYERS SQUIBB COMPANY, CHIRON  
CORPORATION, ELI LILLY AND COMPANY,  
FOREST PHARMACEUTICALS INC., FUJISAWA  
PHARMACEUTICAL COMPANY, LTD.,  
GENENTECH, INC., SMITHKLINE BEECHAM  
CORPORATION D/B/A GLAXOSMITHKLINE  
CORPORATION, JANSSEN PHARMACEUTICAL,  
MEDIMMUNE, INC., MERCK & CO., INC.,  
NOVARTIS AG, ORTHO MCNEIL  
PHARMACEUTICALS, PFIZER INC.,  
PHARMACIA CORPORATION, PURDUE  
PHARMA, L.P., SANOFI-SYNTHELABO, INC.,  
SCHEIN PHARMACEUTICAL INC., SCHERING-  
PLOUGH CORP., SMITHKLINE BEECHAM  
CORPORATION, TAP PHARMACEUTICALS,  
WYETH, and DOES 1-100,

Defendants.

03 229  
Index No.

HURLEY,

COMPLAINT

ORENSTEIN, M.J.

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CLERK  
U.S. DISTRICT COURT  
EASTERN DISTRICT  
OF NEW YORK

Plaintiff, the County of Suffolk (hereinafter "Suffolk"), brings this action under the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, the Social Security Act, 42 U.S.C. §1396r-8, state statutory and common law to recover monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, treble and punitive damages suffered as a result of defendants' unlawful scheme to overcharge for

prescription medications paid for by Medicaid. Suffolk County is required by New York State law to pay 25% of its Medicaid costs, including the cost of prescription drugs ("pharmacy costs"). Suffolk County is also required to balance its budget annually. Every dollar wrongfully spent on Medicaid could have properly been allotted to other public needs. Suffolk's claims as to itself and its own actions are based upon its personal knowledge. All other allegations are based upon information and belief pursuant to the investigation of counsel.

## **I. INTRODUCTION**

1. Each of the defendants is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States. The principal payors for such prescription pharmaceuticals are federal, state and local governments (under the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients). Plaintiff is a municipal corporation and local government required by New York State law to contribute 25% towards its Medicaid costs.

2. For the last decade, defendants have conspired with others in the pharmaceutical distribution chain, including but not limited to pharmacies, physicians, hospitals and other medical providers (hereinafter "providers"), to collect inflated prescription drug payments from Suffolk.

3. It is standard practice that federal Medicare and Medicaid Programs, state and local Medicaid entities (such as Suffolk), Third Party Payors and patients reimburse providers for prescription drugs based upon the Average Wholesale Price ("AWP") for such drugs, as published

and reported by third-party publications such as *Red Book*, *Blue Book* or *Medispan* (hereinafter collectively referred to as “publishers”).

4. Suffolk pays for most prescription drugs based on AWP pursuant to federal and state statute and regulation. Because defendants artificially inflate the AWP in order to manipulate reimbursements, plaintiff has made excessive payments.

5. Pharmaceutical companies self-report the AWP to publishers which then publish the AWP provided to them. The AWP is not independently determined by the publishers.

6. By federal and state statute and regulation, and industry practice, the AWP is intended and required to be based upon and directly related to actual prices paid by providers to pharmaceutical manufactures (or wholesalers) for such prescription drugs.

7. In fact, as recently has been revealed by extensive and ongoing Congressional and federal investigations, pharmaceutical manufacturers (including defendants) have engaged in a scheme and enterprise, commencing in 1993 if not earlier, involving the fraudulent reporting of fictitious AWP's for certain prescription pharmaceuticals including prescription pharmaceuticals covered by Medicare and Medicaid and paid for by Suffolk.

8. The fraudulent AWP Scheme has involved the reporting by each defendant of false and inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting and overstating the actual prices paid to defendants by providers.

9. The fraudulent scheme devised and initiated by defendants and implemented by its co-conspirators was effectuated by: (i) overstating the AWP for drugs for which Medicaid

provides reimbursement based upon AWP ("Covered Drugs");(ii) marketing and promoting the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; (iii) providing providers with free samples and financial incentives to over-prescribe Covered Drugs or prescribe Covered Drugs in place of competing drugs; and (iv) overcharging the Medicaid program for illegally inflated Covered Drugs reimbursements.

10. According to one member of the Congressional Ways and Means Committee, describing the conduct of one defendant herein:

The price manipulation scheme is executed through Bristol's falsely inflated representations of average wholesale price ("AWP"), direct price ("DP"), and wholesale acquisition cost ("WAC"), which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP, DP, and WAC versus the true price providers are paying, is regularly referred to . . . as "the spread."

\* \* \*

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

(February 27, 2001 letter from Representative Pete Stark to Peter Dolar, President, Bristol-Myers Squibb Co.).

11. Suffolk alleges upon information and belief that, in many instances, the AWP reported by the defendant pharmaceutical manufacturers bears a minimal relationship to the prices actually paid by providers and is “made up” by corporate pricing committees literally out of “thin air” for the purpose of manipulating pharmaceutical markets and increasing market share. Many of the facts underlying this fraud are peculiarly within defendants’ control.

12. In addition, pursuant to 42 U.S.C. § 1396r-8, each of the defendants was required to report to the Secretary of Health and Human Services the lowest price it sold a drug to any for-profit entity. Each defendant agreed to offer the Medicaid Program its “best price.” A like requirement appears in New York State’s Medicaid Statute. *See* New York Social Services Law § 367-(a)(7)(d). Yet, defendants excluded from their reporting of best prices certain drugs offered at discounts or other rebates that would have reduced the price paid. They did so to avoid paying rebates to Medicaid and to avoid having to disclose the true best price, which would have required a reduction in the reported AWP.

13. Thus, defendants knowingly have violated federal and state statutes by deliberately publishing false, inflated and misleading price data that directly results in excessive payments by Suffolk. Neither federal nor state statutory schemes, even to the extent they base reimbursement on AWP’s, permit defendants to engage in this widespread, concerted fraud. Suffolk would not have been damaged if defendants complied with the existing federal and state laws.

14. As a result of the fraudulent and illegal manipulation of AWP for covered drugs by defendants, defendants have reaped billions of dollars in illegal profits at the expense of



American consumers, taxpayers and entities such as plaintiff that make pay reimbursements for Medicaid pharmacy costs.

## **II JURISDICTION AND VENUE**

15. This action is brought for and on behalf of the County of Suffolk, pursuant to, *inter alia*, the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*, New York's Gen. Bus. Law § 349, *et seq.*, and for breach of contract, unjust enrichment, Medicaid fraud, and common law fraud.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* and the Social Security Act, 42 U.S.C. § 1396 *et seq.* This Court has supplemental jurisdiction over plaintiff's state law claims pursuant to 28 U.S.C. § 1367.

17. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) because defendants do business and are qualified to do business in this District; certain acts giving rise to the claims asserted in this Complaint occurred within this District; and the illegal actions of defendants, as alleged in this Complaint, caused damage to plaintiff within the District.

## **III PARTIES**

18. Plaintiff, the County of Suffolk, New York is and was at all relevant times, a body corporate and politic organized and existing under the laws of the State of New York with its principal place of business located at the County Complex, Veterans Memorial Highway, Hauppauge, New York.

19. Defendant Abbott Laboratories, Inc. ("Abbott") is a highly diversified health care corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott conducts extensive business in the State of New York, including in the County of Suffolk. Abbott manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Depakote® (psychotropic drug) and Kaletra®.

20. Defendant AG Scientific Inc. ("AG Scientific") is a California corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. AG Scientific's principal place of business is 6450 Lusk Blvd., Suite E102, San Diego, California 92121. AG Scientific conducts extensive business in the State of New York, including in the County of Suffolk. AG Scientific manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Clozapine®.

21. Defendant Agouron Pharmaceuticals Inc. ("Agouron") is a California corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Agouron's principal place of business is 10350 North Torrey Pines Road, Suite 100 La Jolla, California 92037. Agouron does extensive business in the State of New York, including in the County of Suffolk. Agouron manufactures and and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Viracept® (HIV treatment).

22. Defendant Amgen, Inc. ("Amgen") is a California corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Amgen does extensive business in the State of New York, including in the County of Suffolk. Amgen manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Enbrel®.

23. Defendant AstraZeneca US is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. AstraZeneca does extensive business in the State of New York, including in the County of Suffolk. AstraZeneca manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Prilosec® and Seroquel®.

24. Defendant Bayer AG ("Bayer") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Bayer conducts extensive business in the State of New York, including in the County of Suffolk. Bayer AG manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Cipro®.

25. Defendant Berlex Laboratories, Inc. ("Berlex") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Berlex's principal place of business is P.O. Box 1000, Montville, New Jersey 07045-1000. Berlex conducts extensive business in the State of New York, including in the County of Suffolk. Berlex Laboratories manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Betaseron®.

26. Defendant Biogen, Inc. ("Biogen") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Biogen's principal place of business is 14 Cambridge Center, Cambridge, Massachusetts 02142. Biogen conducts extensive business in the State of New York, including in the County of Suffolk. Biogen manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Avonex®.

27. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Bristol-Myers's principal place of business is 345 Park Avenue, New York, New York. Bristol-Myers does extensive business in the State of New York, including in the County of Suffolk. Bristol-Myers manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Gluophage®, Sustiva®, Pravachol®, Zevit®.

28. Defendant Chiron Corporation ("Chiron") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products for cancer and infectious disease. Chiron's principal place of business is 4560 Horton Street, Emeryville, CA. Chiron does extensive business in all of the counties of the State of New York, including the County of Suffolk. Chiron manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Tobin®.

29. Defendant Eli Lilly and Company ("Lilly") is an Indiana corporation whose principal business is the development, manufacture and sale of health care products including

pharmaceuticals. Lilly does extensive business in the State of New York, including in the County of Suffolk. Lilly manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Zyprexa®, Prozac® and Axid®.

30. Defendant Forest Pharmaceuticals Inc. ("Forest") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Forest's principal place of business is 13600 Shoreline Drive, St. Louis, Missouri 63045. Forest conducts extensive business in the State of New York, including in the County of Suffolk. Forest manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Celexa®.

31. Defendant Fujisawa Pharmaceutical Co., Ltd. ("Fujisawa") manufactures and sells pharmaceutical products, foods, and chemical and agrochemical products. Through its subsidiary Fujisawa Healthcare, Inc., headquartered at Three Parkway North, Deerfield, IL, Fujisawa conducts extensive business in the State of New York, including in the County of Suffolk. Fujisawa manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Prograf®.

32. Defendant Genentech, Inc. ("Genentech") is a Delaware corporation whose principal business is the discovery, development, manufacture, and sale of pharmaceuticals. Genentech's principal place of business is One DNA Way, South San Francisco, CA. Genentech conducts extensive business in the State of New York, including in the County of Suffolk. Genentech manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Pulmozyme®.

33. Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline Corporation ("GSK"), is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals. GSK does extensive business in the State of New York, including in the County of Suffolk. GSK includes the corporation that did business as Glaxo Wellcome, Inc. ("Glaxo"), which was a highly diversified health care company whose principal business was the development, manufacture and sale of health care products and services, including pharmaceuticals. Glaxo, at certain times relevant to this complaint, conducted extensive business in the County of Suffolk including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein. GSK manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Wellbutrin®, Serevent®, Paxil®, Epivir® and Augmentin®.

34. Defendant Janssen Pharmaceutical ("Janssen") is a New Jersey corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Janssen's principal place of business is 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen conducts extensive business in the State of New York, including in the County of Suffolk. Janssen manufactures and sells prescription drugs with false and inflated AWPs that are paid for by Medicaid in Suffolk County, including such medications as Risperdal®.

35. Defendant MedImmune, Inc. ("MedImmune") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. MedImmune conducts extensive business in the State of New York, including in the County of Suffolk. MedImmune's principal place of business is 35 W. Watkins Mill Road,

Gaithersburg, Maryland 20878. MedImmune manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Synagis®.

36. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Merck's principal place of business is One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100. Merck conducts extensive business in the State of New York, including in the County of Suffolk. Merck manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Crixivan®, Vioxx® and Zocor®.

37. Defendant Novartis AG ("Novartis") is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Novartis conducts extensive business in the State of New York, including in the County of Suffolk. Novartis manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Clozaril®.

38. Defendant Ortho McNeil Pharmaceuticals ("Ortho") is a highly diversified health care company incorporated in New Jersey whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Ortho's principal place of business is McKean and Welsh Roads, Spring House, Pennsylvania 19477. Ortho conducts extensive business in the State of New York, including in the County of Suffolk. Ortho manufactures and sells



prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Levaquin® and Topamax®.

39. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Pfizer's principal place of business is 235 East 42<sup>nd</sup> Street, New York, New York 10017. Pfizer does extensive business in the State of New York, including in the County of Suffolk. Pfizer manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Lipitor®, Neurontin®, Norvasc®, Zoloft® and Zyrtec®.

40. Defendant Pharmacia Corporation ("Pharmacia") is a New Jersey corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Pharmacia's corporate headquarters are located at 100 Route 206 North, Peapack, New Jersey. Pharmacia does extensive business in the State of New York, including in the County of Suffolk. Pharmacia manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Celebrex® and Ambien®.

41. Defendant Purdue Pharma, L.P. ("Purdue") is a pharmaceutical company whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Purdue's principal place of business is One Stamford Forum, 201 Tresser Boulevard, Stamford, CT. Purdue conducts extensive business in the State of New York, including in the County of Suffolk. Purdue manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Oxycontin®.



42. Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Sanofi's principal place of business is One Well Street, New York, New York 10286. Sanofi conducts extensive business in the State of New York, including in the County of Suffolk. Sanofi manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Plavix®.

43. Defendant Schein Pharmaceutical, Inc. ("Schein") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Schein conducts extensive business in the State of New York, including in the County of Suffolk. Schein manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Singulair®.

44. Defendant Schering-Plough Corp. ("Schering") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Schering is a New Jersey corporation, whose headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough does extensive business in the State of New York, including in the County of Suffolk. Schering-Plough manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Claritin®.

45. SmithKline Beecham Corporation ("SmithKline") was a highly diversified health care company whose principal business was the development, manufacture and sale of health

care products and services, including pharmaceuticals. It is now part of GSK. SmithKline conducted extensive business in the State of New York, including in the County of Suffolk. This Court has personal jurisdiction over SmithKline and venue is properly laid in this county, to the extent GSK is not responsible for the wrongful acts of SmithKline.

46. Defendant Tap Pharmaceuticals ("Tap") is a highly diversified health care company whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Tap conducts extensive business in the State of New York, including in the County of Suffolk. Tap's principal place of business is 675 North Field Drive, Lake Forest, Illinois 60045. Tap Pharmaceuticals manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Prevacid®.

47. Defendant Wyeth is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Wyeth is a Delaware corporation whose principal place of business is Five Giralda Farms, Madison, NJ. Wyeth conducts extensive business in the State of New York, including in the County of Suffolk. Wyeth manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Suffolk County, including such medications as Effexor XR®.

#### **AS YET UNNAMED CO-CONSPIRATORS AND DOE DEFENDANTS**

48. Various other individuals, partnerships, sole proprietors, business entities, companies, and corporations, presently unknown to Suffolk and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-

conspirators and aided, abetted, or participated with defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by Suffolk.

49. Except as described herein, plaintiff is, as yet, ignorant of the true names, capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-100 inclusive and, therefore, sues these defendants by such fictitious names. Suffolk will amend this Complaint to allege the true names and capacities of the Doe defendants when ascertained.

50. Defendants unknown at this time may include independent pharmacies, dispensers, and other medical providers who prescribed drugs and received inflated Medicaid reimbursements and engaged in fraudulent billing practices, as well as various other persons, partnerships, sole proprietors, firms, corporations and individuals that may have participated as co-conspirators with defendants in the offenses alleged in this complaint and may have performed acts and made statements in furtherance of the alleged illegal conduct.

51. Each of the defendants designated herein as a Doe defendant is legally responsible in some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court if necessary to amend this Complaint to reflect the true names and capacities of the defendants designated herein as Does when such identities become known.

#### IV. GENERAL ALLEGATIONS

52. The allegations contained herein apply generally to all defendants.

##### A. The AWP System

53. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers, including hospitals (collectively referred to hereinafter as "providers").

54. This case concerns "Covered Drugs", which are those drugs for which pursuant to N.Y.Soc. Serv. Law § 367-a(9), Suffolk's Medicaid pharmacy cost reimbursement rate is pegged to AWP. In New York's statutory scheme, AWP is also known as "Estimated Acquisition Cost" or "EAC."

55. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, Medicaid, insurers and patients. At all times relevant hereto, defendants knew that the Medicare/Medicaid programs rely on published AWP's to reimburse providers for drugs.

56. AWP's are published for each drug identified by a National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWP's for the tens of thousands of drugs. Medical Economics Company Inc. publishes the *Drug Topics Red Book* (the "*Red Book*"). First Data Bank compiles the *National Drug Datafile*. There is also the *American Druggist First Databank Annual Director of*

*Pharmaceuticals and Essential Director of Pharmaceuticals* (the "*Blue Book*") and Medi-Span's Master Drug Database (collectively referred to herein as the "publishers").

57. In periodically announcing the AWP for each drug, the publishers publish the prices that are supplied to them by the defendants for their respective drugs. The forward to the 1999 edition of the *Red Book* stated that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted."<sup>1</sup> A June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the AWP generally is not independently determined by the Publishers. Defendants control the prices listed as the AWP for each drug.

58. A system that bases its reimbursement rates for drugs on the published AWP is dependent on the honesty of the drug manufacturers.

59. Extensive and ongoing federal and Congressional investigations, recently have revealed that numerous pharmaceutical manufacturers (including certain of the defendants named

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<sup>1</sup> As if in acknowledgment of the scheme, the forward to the 2002 Red Book now reads

All pricing information in Red Book is furnished by manufacturers, distributors, and other suppliers. **While great care has been taken in compiling the data, we conduct no independent review and therefore cannot guarantee the accuracy of these prices.** We continue to regard AWP as one guideline in the ~~R~~ pricing equation and **to encourage the dissemination of fair, accurate prices by all suppliers.**

See 2002 Drug Topics® Red Book, Forward (emphasis added).

herein and others not yet named) have engaged in a scheme involving the fraudulent reporting of AWP for certain prescription pharmaceuticals including but not limited to prescription pharmaceuticals covered by Medicaid.

60. Specifically, defendants' AWP Scheme involves the reporting by each defendant of inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting the actual prices paid to defendants by providers, in violation of federal and state law.

61. Defendants knew that they could directly control, fabricate and inflate the AWP for their drugs at any time by forwarding to the Publishers a new and higher AWP. Actual transaction price data -- the amounts actually paid by providers for drugs -- was not publicly available, and defendants have kept this information (on which AWP should have been calculated) highly confidential and secret. This made it practically impossible to calculate Medicaid reimbursements based on anything other than AWP. Defendants' concealment of actual price data is one of the many reasons the facts underlying defendants' fraud are peculiarly within defendants' control, and why any applicable statute of limitations should be tolled.

62. Plaintiff alleges upon information and belief that, in many instances, the AWP reported by defendants bears little or no relationship to the prices actually paid by providers, in direct violation of federal and state law. Rather, the reported AWP for covered drugs were simply fabricated in furtherance of defendants' scheme to generate the profit spread to providers, to increase defendants' profits at the expense of Suffolk and other Medicaid payors, and to control the market for their products.

63. Defendants' pattern of fraudulent conduct in artificially inflating the AWP's for the Covered Drugs (sometimes referred to herein as the "AWP Scheme") directly and foreseeably caused Suffolk to substantially overpay for those drugs, given Suffolk's federal and state statutory obligations, of which defendants were aware.

#### **B. The Medicaid Statutory Scheme**

64. Medicaid was established by Title XIX of the Federal Social Security Act (the "Act"), 42 U.S.C. 1396, *et seq.* (the "Medicaid Program"). The Act mandates the establishment of minimum health and safety standards which must be met by providers and suppliers, such as defendants, participating in the Medicaid Program. While participation in Medicaid is voluntary, once a state agrees to participate, as New York has (most recently at New York Social Services Law § 363 *et seq.*, as amended 1998) the state must comply with all federal statutory requirements.

65. Among other services and supports, the Medicaid Program pays for certain prescription drugs for those who qualify. Under New York law, N.Y. Social Services Law § 367-a, if such a covered drug is a multiple source prescription drug (generic) or a brand name prescription drug for which no upper limit has been set by the Federal Health Care Financing Administration ("HCFA") (now known as the Centers for Medicare & Medicaid Services (CMS))<sup>2</sup>, then reimbursement under Medicaid is the lower of the providers' usual and customary charge to the general public or the estimated acquisition cost (EAC), of the drug plus a reasonable dispensing fee.

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<sup>2</sup> CMS is a division of the United States Department of Health and Human Services ("HHS") and responsible for the administration of the Medicaid and Medicare programs. HHS is responsible for the funding, administration and supervision of those programs.



66. The dispensers' usual and customary charge is not available anywhere. As a result and, as a practical matter, reimbursement is based entirely upon EAC.

67. The EAC is calculated by using the AWP for a drug less a percentage discount. New York's Social Services Law § 367-a(9) expressly defines EAC as "the average wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less ten percent thereof, and updated monthly by the department." The 2002 New York Medicaid Reimbursement Rate is  $AWP - 10\% + \$3.50/\$4.50$  (dispensing fee).

68. Thus, Suffolk County reimburses providers for Covered Drugs at an amount that is based upon the Covered Drugs' Estimated Acquisition Cost ("EAC") or Average Wholesale Price ("AWP"), as published and reported by the publishers discussed above. As alleged, given that these AWP's are false and inflated, Suffolk has been overcharged.

69. In 2001, only two of Suffolk's leading Medicaid reimbursed drugs (Albuterol Aer 90 MCG and Augmentin Tab 875 ml) had HCFA upper limits established. See Exhibit A hereto. For all other drugs where Medicaid reimbursements were made by Suffolk, *id.*, such payments were based on AWP and therefore wrongfully and falsely inflated pursuant to the scheme alleged herein. As Exhibit A makes plain, this means that the vast majority of at least Suffolk's top Medicaid reimbursements were inflated.

70. There is another aspect to the Medicaid Statutory Scheme implicated here. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of Health



and Human Services. Pursuant to the rebate agreement, the manufacturer promises to report to Medicaid its "best price." The statute defines the best price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and does not include "prices that are merely nominal in amount."

71. Upon information and belief, each defendant herein entered into such a rebate agreement with the Secretary of Health and Human Services. In that agreement, each agreed to comply with Section § 1396r-8, and hence:

(a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary;

(b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid"; and

(c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

72. New York Social Services Law § 367-(a)(7)(d) expressly provides that where a manufacturer had entered into a rebate agreement, as outlined above, Medicaid reimbursements shall be made only pursuant to the terms of that rebate agreement.

73. 42 U.S.C. § 1396r-8(c)(ii) expressly provides that “any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information.”

74. Suffolk, like any Medicaid payor, was an intended third party beneficiary of these rebate agreements.

**C. Defendants’ Use of AWP Scheme To Corrupt Medicaid And Earn Illegal And Excessive Profits**

75. After execution of the rebate agreement required pursuant to 42 U.S.C. § 1396r-8, each Defendant reported its average manufacturer’s price in each quarter. Yet, consistent with their artificial inflation of AWP to publishers, defendants did not report the actual “best price” but, instead, excluded from best price discounts and other inducements offered to providers to increase use of a drug being reimbursed by governmental entities at AWP.

76. The AWP scheme succeeds precisely because providers are able to obtain drugs at prices significantly below current Medicaid reimbursements. Most manufacturers sell drug products to physicians and other suppliers at a discount from AWP. Sometimes these discounts are substantial.

77. The widely available prices available from wholesalers and group purchasing organizations (“GPOs”) for covered drugs are considerably less than the AWP used to establish the Medicaid reimbursement. For most of the high-expenditure or high volume physician-administered

drugs, widely available discounts from AWP range at the low end from 13 percent to 34 percent. Recent, ongoing federal investigations reveal much greater discounts, sometimes as high as 85%. Providers who have been identified as low-volume billers for certain drugs can also purchase drugs for considerably less than the Medicaid reimbursement.

78. Upon information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs. These inducements, including educational grants, volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug item might really only cost the purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a "grant," "rebate" or "credit memo" in the amount of \$50, the transaction would truly cost just \$5 per unit net. Through all these "off-invoice" means, drug purchasers were provided the substantial discounts that induced their patronage while maintaining the fiction of a higher invoice price—the price that corresponded to reported AWP and inflated reimbursement from Medicaid. One example is this from Bayer:

BAYER: "I have been told that our present Kogennate price, \$.66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume.

79. "GPOs" that pool the purchase of multiple entities to negotiate prices with wholesalers or manufacturers. GPOs may negotiate different prices for different purchasers, such as physicians, suppliers, or hospitals.

80. Manufacturers or wholesalers also offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers also establish "chargeback" arrangements for purchasers, which result in the AWP overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

81. Thus, while federal and state Medicaid statutes law require the defendants to provide quarterly rebates if they charge more than the lowest or "best price" offered to any commercial customer, the defendants routinely fail to do. This is because defendants know that, due to practical problems with ascertaining actual cost charges or street prices, Medicaid administrators routinely determine the allowable payment for a prescription drug based upon the AWP reported by the applicable pharmaceutical manufacturer. *See* New York Social Services Law §367-a(9). This is due to practical problems with ascertaining actual cost charges, or street prices.

82. Thus, under New York Medicaid rules providers receive AWP - 10% + a dispensing fee, regardless of the drug's actual cost to them. This practice of taking advantage of the difference between the supplier's purchase price and the amount that a physician receives via Medicaid is referred to internally by defendants as "marketing the spread."

83. The actual price that providers pay for approved drugs is not disclosed anywhere, including to Medicaid local administrators. This is among the underlying facts regarding

defendants' fraud that is peculiarly within defendants' control, and why any applicable statute of limitations must be tolled.

84. In a September 21, 2000, report, the United States Government Accounting Office ("GAO") found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger—65 percent and 86 percent less than AWP.

85. Two drugs, *albuterol* and *ipratropium bromide* for respiratory conditions, accounted for many of the pharmacy-supplied drugs paid for by Medicaid nationwide. In 2001, they were available to pharmacy suppliers at prices that averaged, respectively, 85 percent and 78 percent less than AWP.

86. Two of the high-volume oral immunosuppressives were available from wholesalers with average discounts of 14 percent and 77 percent.

87. The September 2001 GAO report specifically implicated the conduct of defendant Amgen with respect to at least one of its drugs, paid for by Suffolk as a Medicaid pharmacy cost *i.e.*, epoetin alfa sold as Epogen®.

88. According to the GAO report, the discounts on physician-billed drugs (based on wholesaler and the GPOs' catalogue prices) were notably lower than Medicaid's payment of ten (10) percent below AWP.

89. Examples of the manipulation of AWP also are contained in the investigative materials compiled by Congressman Pete Stark (D-Calif.):

(a) In the 2000 edition of the Red Book, Defendant Bristol reported an AWP of \$1,296.64 for one 20mg/ml, 50ml vial of Vepecsid (Etoposide) for injection, while selling the exact same drug in the same quantity to a GPO for \$70. This represents a spread between Bristol's falsely inflated AWP and the real price of \$1,226.64. Bristol is a defendant herein.

(b) Effective January 10, 1995, Defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously fully discounting this increase to providers. The net effect of these adjustments was to increase the amount of reimbursements available to providers from Medicaid and others whose reimbursement is based on the AWP. Because the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in the AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce providers to purchase Zofran based on the opportunity to receive increased reimbursement from Medicaid and other third party payors.

90. Other examples include Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, a defendant herein, which had a reported AWP of \$241.36 as of April 2000. The real wholesale price was \$33.43. In 1997, when the reported AWP for this drug was \$946.94, it was being offered to physicians for as low as \$152.00.

91. Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was \$28.38; DOJ found that retailers were buying it for \$1.70.

92. Amikacin, used to treat an infection that HIV+ people are susceptible to and manufactured by defendant Abbott, had an AWP of \$54.56. The actual best price was \$6.75. Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14.

93. The Stark investigation is just one of many. Defendant Bayer agreed to settle claims asserted by the U.S. Government arising from this practice. According to the Department of Justice's press release:

The government's investigation of the allegations revealed that Bayer beginning in the early 1990s falsely inflated the reported drug prices -- referred to by the industry as the Average Wholesale Price (AWP), the Direct Price and the Wholesale Acquisition Cost -- used by state and federal governments to set reimbursement rates for the federally and state funded Medicaid Program. By setting an extremely high AWP and, subsequently, selling the product to doctors at a dramatic discount, Bayer enabled physicians to receive excess reimbursement from private and government insurers. . . .

The investigation further revealed that Bayer was engaging in a practice referred to as "marketing the spread" that also has the effect of discouraging market competition from companies that do not inflate AWP's as a way of attracting doctors to their products. The department's probe also showed that some physicians and home health companies ignore the products of companies that refuse to create these profit windfalls for customers. The parties also are settling allegations that Bayer knowingly underpaid the Medicaid Program for rebates owed by it to the states. The Medicaid Rebate program was initiated in 1991 to require drug companies to pay quarterly rebates to states in a way that accounts for discounts that drug companies give to customers. Under the program, Bayer was required to report the best price offered to any commercial, for-profit customer to the government and calculate a quarterly rebate based, in part, upon the



best price. The investigation revealed that certain of Bayer's customers received discounts unaccounted for by the multi-national pharmaceutical company in its quarterly best price calculations thereby allowing Bayer to underpay the rebates it owed.

94. The government's investigation had uncovered substantial evidence that Bayer's fraudulent practices were widespread. For example, in a report published by DIIHS, the DOJ documented at least 10 instances where the published AWP for drugs manufactured by Bayer were substantially higher than the actual prices listed by wholesalers.

95. In addition to marketing the spread, Bayer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Bayer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

96. As set forth above, Bayer's scheme to inflate its reported AWP and market the resulting spread to increase the market share of its drugs and its use of other "off invoice" rebates and financial inducements to its customers has resulted in excessive overpayments by Plaintiffs and the Class.

#### **AstraZeneca**

97. Defendant AstraZeneca has engaged in an ongoing deliberate scheme to inflate AWP. One example, according to the September 2001, GAO report, the discount from AWP for medical providers who purchased AstraZeneca's Zoladex and billed Medicare /Medicaid was between 21.9% and 22.3%.



98. Internal AstraZeneca documents reveal that AstraZeneca was directly marketing the spread to physicians.

99. A memo announcing price changes for Zoladex states:

"We have raised AWP and AWC by 7% and have increased our discount level higher at all purchasing tiers.

Thus, at the same time AstraZeneca was raising the AWP for Zoladex, it was lowering the real price to providers (by giving bigger discounts), which served to widen the spread.

100. Another document sets forth the difference between the purchase price and the AWP at various volume levels. Note that even with no volume discount, a provider is still making at least a \$71.00 profit per unit on Zoladex ( $\$358.55 - 286.84 = \$71.71$ ):

#### ZOLADEX PRICING

UNITS	REPORTED AWP	STREET PRICE	DISCOUNT	LESS 2% DISCOUNT
1-5	\$358.55	\$286.84	0%	\$281.10
6-11	\$358.55	\$269.63	6%	\$264.24
12-23	\$358.55	\$261.02	9%	\$255.80
24-47	\$358.55	\$252.42	12%	\$247.37
48-59	\$358.55	\$243.81	15%	\$238.93
60-71	\$358.55	\$235.21	18%	\$230.50
72+	\$358.55	\$229.47	20%	\$224.88

101. The same document goes on to tout the practice's ability to make more profit, or return on investment, by exploiting the AWP scheme:

Thank you for your time and listening ear on Monday, April 17. As discussed, I am offering a proposal to switch Lupron patients to Zoladex. Zeneca Pharmaceuticals now has new volume pricing, with a 20% maximum discount, for Zoladex. What this will offer the practice is an opportunity to save money, realize a better return on investment, achieve the same profit you currently have with our competitor and free up a substantial amount of working capital. Zoladex will also save the patient money and the system money.

Based on a comparison of Zoladex and Lupron, if 480 depots [bulk units] are used annually, Zoladex will save the practice \$57,177.60 a year. Your dollar return to the practice is now slightly higher with Zoladex. This rate of return for Zoladex is now 59% compared to Lupron's 39%.

102. Another AstraZeneca document even more explicitly demonstrates to providers how they can profit from the AWP scheme, in excess of \$64,000 per year:

#### ZOLADEX

<u>Direct Pricing</u>	<u>Medicare AWP</u>	<u>\$\$\$Return/% Return</u>
72+ \$244.88	\$358.55	\$133.67 59%
72x\$224.88=\$16,191.38	72x\$358.55=\$25,815.60	\$9,624.24 59%
<i>based on your use of 480 depots annually, with our 2% discount these are the comparisons</i>		
\$107,942.40	\$172,104.00	\$64,161.60 59%

103. AstraZeneca, through its employees and agents, also provided millions of dollars worth of free samples of its drugs to providers. The free samples would be used to offset the total cost associated with purchases of its drugs, thereby increasing the spread, while also concealing the actual cost of the drug from Suffolk. Moreover, at least as to Zoladex®, AstraZeneca sales representatives specifically told providers that they could and should bill for the free samples.

104. A written proposal from AstraZeneca Sales representative Randy Payne dated July 17, 1995 encourages a urology practice to switch all of their patients to Zoladex and states: "AS AN ADDED INCENTIVE, ZENECA WILL PROVIDE YOU WITH 50 FREE DEPOTS (over \$11,900 worth of product) FOR THE INITIAL CONVERSION TO ZOLADEX."

105. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that AstraZeneca sales representatives had given the doctor. The indictment alleges that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca and (ii) provided the New Jersey Doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

106. Upon information and belief, the Zolodex example is merely one of the ways in which AstraZeneca wrongfully and falsely has inflated its reported AWP's. This unlawful activity, has resulted in excessive overpayments by Suffolk.

107. The foregoing are merely examples of this pervasive scheme. The Office of Inspector General ("OIG") 2001 review estimated that actual price of prescription drugs was, at the low end, 21.84% below the reported AWP across the board. The OIG estimated that as much as \$1.08 billion nationwide could have been saved for the 200 most frequently reimbursed drugs in Calendar Year 1999, if reimbursement had been based on a greater percentage discount off of AWP, or actual price. Other reports, such as a September 21, 2000 GAO Report have determined that actual prices for top Medicaid/Medicare drugs such as Albuterol (one of Suffolk's top Medicaid pharmacy costs) and Ipratropium bromide are 85% and 75% less than their AWP's. Applying this

range of percentages to Suffolk County's Medicaid result in millions of dollars of illegal overcharges since 1995 alone.

**D. Motivation for Defendants' AWP Pricing Scheme**

108. The purpose and intent of defendants' fraudulent AWP Scheme is to manipulate and thereby increase the amount of reimbursement received by providers of drugs manufactured and sold by defendants.

109. Specifically, defendants' AWP Scheme contemplates that (a) defendants will intentionally report falsely and fraudulently inflated AWP prices for these drugs to industry publications; and (b) defendants will actually charge providers amounts for these drugs that are substantially less than the AWP that defendants have fraudulently reported.

110. The provider then receives reimbursement from Medicaid, based upon the fraudulently inflated AWP. This circumstance results in a substantial financial incentive to the provider, representing the difference between the inflated AWP-based reimbursement to the provider and the significantly lower direct price charged by defendants to the provider.

111. Defendants refer to the amount received by the provider resulting from the difference between the fraudulently inflated AWP reimbursement and the price actually paid by the provider as the "spread."

112. Each of the defendants has sought to manipulate the market for drugs at issue by inducing providers to prescribe these drugs, rather than competing drugs, because of the higher "spread" resulting from the falsely and fraudulently inflated AWP.

113. By participating in the AWP Scheme, defendants seek to influence providers to prescribe the drug with the greatest "spread" between the AWP and the actual direct price paid by the provider to the manufacturer. In fact, defendants have greatly increased their profits by manipulating the AWP to create falsely inflated "spreads", which result in financial incentives to providers to prescribe specific drugs subject to the AWP Scheme.

114. The manipulation of AWP at the expense of Medicaid is further revealed when the defendants sell drugs that are not reimbursed by Medicaid. In these circumstances, the drug companies often report accurate AWP's and actually compete with other drug companies on the basis of having a lower AWP than the other company. The company with the lower AWP will urge physicians to consider the cost to the patient when selecting drugs and promote its lower AWP as a selling tool. Thus, when Medicaid is not involved, defendants often ensure that their AWP's are accurate so as to compete for market share based on price.

115. Defendants were aware that providers would purchase and utilize products that have the widest spread between the providers' true costs and the reimbursement paid by third parties. All defendants made representations of their AWP for various drugs, which representations were not accurate. In doing so, defendants hoped that providers would view the inflated AWP as a reason for selecting their drug, defendants also knew that this selection would be at the expense governmental payors, like Suffolk.

116. For example, an April 2002 GAO report focusing on sales of a drug in Florida found that Medicaid usage of Vancomycin nearly doubled when Abbott raised the AWP. And when Bayer retained its spread on Whin Rho while other manufacturers did not, its use "skyrocketed."

117. This is further demonstrated by defendant SmithKline Beecham and TAP:

SMITHKLINE: "In the clinic setting however, since Medicare [like Medicaid] reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP. . . . Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of \$50.27 for the medication alone. . . . From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regiments."

TAP: "As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of. NWI Urology has 180 patients on Lupron."

118. Thus, each of the defendants has participated in a scheme whereby each would publish in the *Red Book*, *Blue Book* and *Medispan* an artificially inflated AWP for a Covered Drug. Each Defendant knew that the AWP's were fictitious, but nevertheless followed course and published their own fictitious AWP pursuant to their express or tacit agreement to do so.

#### **V. CONGRESSIONAL AND OTHER FEDERAL INVESTIGATIONS AND ACTIONS**

119. The United States Department of Justice ("DOJ"), the United States General Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating defendants and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWP's and for offering illegal incentives to providers.

120. The United States Congress recently has been investigating defendants' wrongful activities. In a letter sent to most, if not each, of the defendants herein and dated October 31, 2000, Congressman Stark stated in pertinent part:

You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . . The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price (AWP) and direct price ("DP") which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims . . . . Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

121. In a letter dated September 28, 2000, sent from the House of Representatives Committee on Ways and Means, Subcommittee on Health to the President of the trade organization known as the Pharmaceutical Research and Manufacturers of America (most of defendants are members), Congressman Stark identified the improper scheme of manipulating AWP's and stated:



This corruptive scheme is perverting financial integrity of the Medicare program and harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit.<sup>3</sup>

122. Congressman Stark made the following five "shocking conclusions":

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a *de facto* improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange *de facto* kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

123. The Stark materials indicate that defendants employed a number of other financial inducements to stimulate the sales of their drugs at the expense of Medicaid. Such inducements include volume discounts, rebates, off-invoice pricing and free goods designed to lower

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<sup>3</sup> The effect on Medicaid is the same given that Medicaid reimbursements also are pegged to AWP. *See, for example*, New York Social Services Law §367-a(9).



the net cost to the purchaser while concealing the actual cost of the drug from reimbursement officials.

124. The DOJ and Congressional investigations are ongoing.

125. On October 13, 2001, the United States Attorney in Boston, Massachusetts announced that TAP Pharmaceutical Products Inc., a corporation that arose from a partnership between Takeda Chemical Industries, Ltd. and Abbott Laboratories, had agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®. As part of the agreement:

(a) TAP agreed to plead guilty to a conspiracy to violations of the Prescription Drug Marketing Act, 21 U.S.C. § 331(t) and 333(b), and to pay a \$290 million criminal fine, the largest criminal fine ever in a health care fraud prosecution. The plea agreement between the United States and TAP specifically stated that TAP's criminal conduct caused the Government losses of \$145,000,000;

(b) TAP agreed to pay the United States Government \$559,483,560 for filing false and fraudulent claims with the Medicare and Medicaid programs as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct;

(c) TAP agreed to pay the fifty states and the District of Columbia \$25,516,440 for filing false and fraudulent claims with the States, as a result of TAP's drug pricing and marketing misconduct, and for TAP's failure to provide state Medicaid programs TAP's best price for Lupron®, as required by law;

(d) TAP agreed to comply with the terms of a sweeping Corporate Integrity Agreement that, among other things, significantly changes the manner in which TAP supervises its marketing and sales staff and ensures that TAP will report to the Medicare and Medicaid programs the true average sale price for drugs reimbursed by those programs;

(e) Abbott and Takeda agreed to cooperate fully with the ongoing government investigation of TAP and its former officers and employees in exchange for the United States declining prosecution of Abbott and Takeda for conduct relating to Lupron®; and

(f) An Indictment was unsealed in the District of Massachusetts against six current or former TAP employees (including an account executive, three District Managers, a National Accounts Manager and the former Vice President of Sales), and a urologist, alleging that they conspired to (i) bill Medicare for free samples of Lupron® and (ii) market Lupron® using the "spread" and the "return to practice" program.

The TAP defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®.

126. At a hearing in the TAP criminal matter, which has an extensive record, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

*United States v. TAP Pharmaceutical Products, Inc.*, No. CR-01-10354-WGY (D. Mass, Dec. 6, 2001).

## **VI. DAMAGES TO SUFFOLK COUNTY**

127. Consistent with nationwide trends, Medicaid costs for Suffolk County have been increasing dramatically each year. Pursuant to N.Y. Soc. Serv. Law § 368-a, Suffolk County is mandated to contribute 25% of its Medicaid costs ("Medicaid Local Share Costs"). The County is billed a total weekly share by the State of New York, and has no input into what it is billed. Suffolk's 2002 Budget includes \$203.5 million for Medicaid Local Share Costs, and it has requested a \$231 million Medicaid budget for 2003, a 13.5% increase. This increase is typical of what other counties in New York State are expecting next year.

128. One of the primary forces, if not the principal force, behind Suffolk's increased Medicaid costs are the cost of prescription drugs, whose prices are inflated pursuant to the AWP scheme alleged herein. Suffolk County's Medicaid pharmacy costs have risen 156% between 1995 and 2001. They totaled nearly \$24 million in 2001 alone. Total pharmacy costs for Suffolk County from 1995 to 2001 are as follows:

<b>Suffolk County Medicaid Pharmacy Costs</b>	
<b>Year</b>	<b>Total Pharmacy Costs</b>
1995	\$9.4 million
1996	\$10.5 million
1997	\$11.9 million
1998	\$13.5 million
1999	\$16.9 million

2000	\$20.0 million
2001	\$23.9 million
January-May 2002	\$10.7 million

Source: New York State Department of Social Services

129. Applying even the most conservative AWP inflation rates of 20-25% to these costs results in millions of dollars in excessive payments by Suffolk for pharmacy costs. As set forth in Exhibit A, all but two of Suffolk's top Medicaid drugs in 2001 (Albuterol Aer 90 MCG and Augmentin Tab 875 mg) were impacted by the AWP scheme.

130. Suffolk County's experience is consistent with the trend nationwide and statewide.

131. Expenditures for prescription drugs in the United States is the fastest growing component of health care, and has risen 15% or more per year over the past several years. Spending on prescription drugs now accounts for around 10% of total spending on health care in the United States. The federal government estimates that drug expenditures will rise 13.5% in 2002, an average of 11.7% a year between 2003 and 2007, and an average of 10.3% a year between 2008 and 2011. If these growth rates are sustained, prescription drugs will increase from 10% to nearly 15% of total national health spending by 2011. By comparison, increased spending on physician and hospital services is projected to decline over time, with physician services up 8.2% in 2002, 6.9% per year between 2003 and 2007 and 6% per year between 2008 and 2011. Spending on hospital care is projected to rise 6.7% in 2002, 5.8% per year between 2003 and 2007, and 5.2% per year between 2008 and 2011.

132. Prescription drug costs under Medicaid are soaring. They increased by an average 18.1% per year from 1997 to 2000, almost three times the rate of increase of all medical services combined. See NIHCM Foundation Report dated June, 2002, "A Primer Generic Drugs, Patents and the Pharmaceutical Marketplace." In 2002, local, state and the federal governments spent \$20 billion on outpatient prescription drugs for Medicaid beneficiaries, up from \$12.1 billion in 1997. Overall, Medicaid spending on prescription drugs rose from \$4.8 billion in 1990 (6.6% of total Medicaid costs) to \$21 billion in 2000. (107% of total Medicaid costs). This increase has been especially dramatic the past three years, with Medicaid pharmacy costs rising nationwide 19% in 2001, 22% in 2000 and 18% in 1999. This contrasts with a 9% increase in total Medicaid expenditures.

133. Thus, this case is brought by Suffolk, *inter alia*, to recover the millions of dollars overpaid as a result of defendants' fraudulent scheme to inflate and maintain the high reimbursement amounts upon which payments made by Suffolk for prescription drugs are based. Defendants' misconduct has unjustly enriched the defendants at the expense of New York's health care system, and ultimately, all New York residents, consumers and taxpayers. In particular, the AWP Scheme directly has cost the County of Suffolk millions of dollars in excess Medicaid pharmacy costs.

## VII. FRAUDULENT CONCEALMENT

134. Each Defendant concealed its fraudulent conduct from Suffolk by controlling the process by which the AWP for Covered Drugs were inflated and reported falsely to Publishers. Defendants prevented Suffolk from knowing what the actual pricing structures for these drugs were,

and failed to inform them of the usage of free samples and the provision of other financial incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, defendants' fraudulent conduct was of such a nature as to be self-concealing.

135. Each Defendant closely guarded its pricing structures and sales figures for their Covered Drugs.

136. Each Defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for the Covered Drugs.

137. Each Defendant worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

138. Each Defendant's efforts to conceal its pricing structures for Covered Drugs is evidence that it knew that its conduct was fraudulent.

139. Thus, each Defendant concealed that (i) its AWPs were highly-inflated (and were inflated solely to cause Suffolk to overpay for the Covered Drugs), (ii) it was manipulating the AWPs of the Covered Drugs, and (iii) the AWPs bore no relationship to the prices paid for, or the pricing structure of, the Covered Drugs and brand name drugs as they were sold to providers and others.

140. Suffolk, unaware of the true facts about the pricing of the Covered Drugs, and statutorily obligated to a 25% Medicaid contribution has paid and continued to pay for them based upon and in reliance on the AWPs, which are the only publicly available pricing figures.

141. Suffolk was diligent in pursuing an investigation of the claims asserted in this Complaint. Through no fault of its own, it did not receive inquiry notice nor learn of the factual basis for the claims in this Complaint and the injuries suffered therefrom until recently.

142. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Suffolk has been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without any fault or lack of diligence on its part. Suffolk could not reasonably have discovered the fraudulent nature of the published AWP's.

143. Defendants were and continue to be under a continuing statutorily-imposed duty to disclose to Suffolk the fact that the published AWP's bore and continue to bear no relationship to the prices or pricing structures for Covered Drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWP's, defendants are stopped from relying on any statutes of limitations.

144. The first four counts assert RICO causes pursuant to 18 U.S.C. §§1962(a), (c) and (d). 18 U.S.C. §1962(a) concerns use of RICO income. 18 U.S.C. §§1962(c) and (d) concern conduct of the pattern of racketeering. The RICO violations were carried out by four distinct and alternative enterprises: the Distribution Enterprise, consisting of defendants and providers, *see* ¶149, *supra*; the Manufacturer-Publisher Enterprise, consisting of defendants and the AWP publishers, *see* ¶¶ 173-174, *supra*; the Publisher Enterprise, consisting of publishers alone, *see* ¶176; and the Medicaid Enterprise, *see* ¶175, which derives from the Medicaid Statutory Scheme described herein and at ¶¶150, 175, *supra*.

## **CLAIMS FOR RELIEF**

### **COUNT 1**

#### **VIOLATIONS OF 18 U.S.C. § 1962(c)-(d)**

145. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

146. This Count, which alleges violations of Sections 1962(c) and (d) of RICO, 18 U.S.C. §§1962(c)-(d), is asserted against the defendants.

147. Defendants are each "persons" as that term is defined in 18 U.S.C. § 1961(3).

148. At all relevant times, in violation of 18 U.S.C. §1962(c), the defendants each conducted the affairs of certain association-in-fact enterprises identified herein as the "Distribution Enterprises" and the "Medicaid Enterprise." The affairs of each enterprise affected interstate commerce and, through a pattern of racketeering activity, defendants conducted the affairs of these enterprises.

#### **The Distribution Enterprises**

149. In accordance with 18 U.S.C. § 1961(4), the Distribution Enterprises are associations-in-fact consisting of (a) various and independent medical providers who prescribed Covered Drugs, and (b) each individual Defendant Drug Manufacturer, including its directors, employees and agents ("The Distribution Enterprises"). The Distribution Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and administering



Covered Drugs to persons whose costs are reimbursed by Suffolk in accordance with Suffolk's obligations under federal and state Medicaid, law, and deriving profits from these activities.

### **The Medicaid Enterprise**

150. In the alternative, at all relevant times and in accordance with 18 U.S.C. §1961(4), an association-in-fact consisting of each of the federal and state agencies that act under federal and state Medicaid statutes, *i.e.*, 42 U.S.C. § 1396 *et seq.* and N.Y. Soc. Serv. L. § 367 *et seq.* constituted a RICO "enterprise," referred to herein as "The Medicaid Enterprise." As alleged herein, each member of the Medicaid Enterprise paid reimbursements for Covered Drugs manufactured by the defendants, and each of these members was victimized by the AWP Scheme.

### **Defendants' Use of the U.S. Mails and Interstate Wire Facilities**

151. At all relevant times, the Distribution Enterprises and Medicaid Enterprise, engaged in and affected interstate commerce because they engage in the following activities across state boundaries: the sale and/or purchase of Covered Drugs, and/or the transmission of sales and marketing literature, and/or the transmission and/or receipt of invoices and payments related to the use of Covered Drugs. During all relevant times, the Distribution Enterprises prescribed and/or administered Covered Drugs to thousands of individuals located throughout the United States. Similarly, during all relevant times, the activities of the Medicaid Enterprise engaged in and affected interstate commerce by establishing a statutory scheme whereby persons who purchased Covered Drugs manufactured and sold by the defendants were reimbursed for the administration of brand name prescription drug benefits based on AWP's.

152. The defendants' fraudulent and wrongful practices, illegal conduct, and violations of RICO were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

153. The nature and pervasiveness of the defendants' AWP Scheme, which was orchestrated from the defendants' corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and interstate wire facilities with various local district managers who oversee the sales forces and the numerous pharmaceutical sales representatives who, in turn, directly communicated with the providers.

154. Many of the precise dates of the defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and, as alleged above, the defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme to defraud and do so below.

155. The defendants' use of the U.S. mails and interstate wire facilities to perpetrate their AWP Schemes involved thousands of communications throughout the relevant time including, *inter alia*:

A. Marketing materials about the AWP's for Covered Drugs and the available spread, which were sent to providers located across the country;

B. Written representations of the AWP's for Covered Drugs made to the *Red Book* and similar publications, which were made at least annually, and in many cases, several times during a single year;

C. Thousands of written and oral communications discussing, confirming, and forwarding free samples of drugs, for which the defendants understood that the providers would unlawfully seek inflated reimbursement.

D. Documents providing information or incentives designed to lessen the prices that providers paid for the drugs, and/or to conceal those prices or the AWP Scheme alleged here;

E. Written communications, including checks, documents discussing and relating to grants, payments of consulting fees, debt forgiveness and/or other financial inducements, as detailed herein;

F. Written and oral communications with U.S. and state Government agencies and private insurers that fraudulently misrepresented what the AWP's for Covered Drugs were, or that were intended to deter investigations into the AWP's for the Covered Drugs or to forestall changes to reimbursement based on something other than AWP's;

G. Written and oral communications with health insurers and patients, inducing payments for Covered Drugs that were made in reliance on AWP's; and

H. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities -the wrongful proceeds of the defendants' AWP Scheme.

I. In addition to the above-referenced RICO predicate acts, the defendants' respective corporate headquarters have communicated by use of the U.S. mails and by interstate wire

facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Complaint.

**Conduct of the RICO Enterprises' Affairs and RICO Conspiracy**

156. During all relevant times, each defendant has exerted control over its particular Distribution Enterprise in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of that particular RICO enterprise, directly or indirectly, in the following ways:

- A. Each defendant has directly controlled the price at which providers purchase its Covered Drugs;
- B. Each defendant has directly controlled the AWP's that are reported in the *Red Book* and similar industry publications;
- C. Each defendant has directly controlled the price at which providers are reimbursed by the Medicaid Program;
- D. Each defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers located nationwide of the profit potential of its Covered Drugs;
- E. Each defendant has directly controlled the marketing and sales scheme to artificially and unlawfully inflate the Medicaid reimbursement rate (and co-payment rate) to induce providers to prescribe Covered Drugs to their patients;
- F. Each defendant has directly controlled the use and distribution of free samples of its Covered Drugs to providers;

G. Each defendant has directly or indirectly controlled the ability of providers to unlawfully seek reimbursement from the Medicaid Program for free samples;

H. Each defendant has relied upon its employees and agents to promote the AWP Schemes alleged herein through the U.S. mails, through interstate wire facilities, and through direct contacts with providers; and

I. Each defendant has controlled and participated in the affairs of its respective Distribution Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs through the use of unlawful inducements to providers.

157. Each of the Distribution Enterprises identified in ¶ 149 of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. Each of the distribution enterprises also had a consensual decision-making structure because, as described above, each defendant knew it was part of the AWP scheme and the providers played an active role in the affairs of the enterprise. In violation of Section 1962(d) of RICO, each of the defendants and each of the providers that were members of the Distribution Enterprises conspired to conduct the affairs of such enterprises through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the defendants and the providers and their overt acts are described in this Complaint.

158. In violation of Section 1962(c) of RICO, each of the defendants and the subject providers have conducted the affairs of each of the Medicaid Enterprises with which they dealt by reporting fraudulently inflated AWP for Covered Drugs, thereby inducing Suffolk, given its federal and state statutory obligations to reimburse costs for Covered Drugs at inflated amounts.

In violation of Section 1962(d) of RICO, each of the defendants and each of the subject providers conspired to conduct the affairs of each of the Medicaid Enterprises with which they dealt through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the defendants and the providers and their overt acts are described in this Complaint.

159. Defendants, through their fraud, controlled the decision-making process of the Medicaid Enterprise

**Pattern of Racketeering Activity**

160. Each of the defendants has conducted and participated in the affairs of its respective Distribution Enterprises and the Medicaid Enterprise through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. §1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud. The defendants' pattern of racketeering likely involved thousands, if not hundreds-of-thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "racketeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively, these violations constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. §1961(5) in which the defendants intended to defraud Suffolk and other medicaid payors, the foreseeable and intended victims of the AWP Scheme.

161. The defendants' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP's for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce providers to prescribe their Covered Drugs to their patients and causing the Medicaid program to pay an artificially-inflated rate of reimbursement for the Covered

Drugs. The defendants' AWP Scheme also consisted of providing free samples of the drugs to providers, instructing (or urging) such providers to bill the Medicaid program for these free samples, and providing the providers with other unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs.

162. The AWP Scheme was calculated and intentionally crafted so as to ensure that the Medicaid Program would be over-billed for the Covered Drugs. In designing and implementing the AWP Scheme, the defendants were at all cognizant of the fact that the entire Medicaid Program and all patients for whom the Covered Drugs are prescribed rely upon the honesty of the defendants in setting the AWP as reported in the *Red Book* and similar publications. Thus, Plaintiff was an intended target and victim of the defendants' AWP Scheme.

163. By intentionally and artificially inflating the AWP and thereby affording the providers with unlawful financial inducements to use the Covered Drugs, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the U.S. mails or interstate wire facilities, the defendants engaged in fraudulent, and unlawful conduct constituting a pattern of racketeering activity.

164. The defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Suffolk and all Medicaid payors. Each separate use of the U.S. mails and/or interstate wire facilities employed by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff. Each of the defendants has

engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Distribution Enterprise and the Medicaid Enterprise.

**Damages Proximately Caused By the Defendants' AWP Scheme**

165. The defendants' violations of federal law and their pattern of racketeering activity have directly, proximately and foreseeably caused Suffolk to be injured in its business or property because Suffolk has paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.

166. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWP's and other information by the same methods in furtherance of their AWP Scheme. As required by federal and state Medicaid law, plaintiff has made inflated reimbursement payments for Covered Drugs based on and/or in reliance on reported and false AWP's.

167. Under the provisions of Section 1964(c) of RICO, the defendants are jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

**COUNT II**

**VIOLATIONS OF 18 U.S.C. § 1962(c)**

168. The County of Suffolk realleges and incorporates by reference the preceding paragraphs as if fully set forth herein.

169. This Count, which alleges violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), is asserted alternatively against the defendants.

170. Defendants are each "persons," as that term is defined in 18 U.S.C. §1961(3).



171. At all relevant times, in violation of 18 U.S.C. § 1962(c), defendants conducted the affairs of certain association-in-fact enterprises identified herein as the "Manufacturer-Publisher Enterprise," the "Medicaid Enterprise", and the "Publisher Enterprise". The affairs of each enterprise affected interstate commerce and, through a pattern of racketeering activity, defendants conducted the affairs of each enterprise.

172. The publishers include, but may not be limited to, (a) Thomson Medical Economics is a division of the Thomson Corporation, a Delaware corporation with its principal place of business located at One Station Place, Stamford, Connecticut, and it is the publisher of the Drug Topics Red Book ("*Red Book*"); (b) First DataBank, Inc., a Missouri corporation, with its principal place of business at 1111 Bayhill Drive, San Bruno, California, and it is the publisher of drug pricing information including, but not limited to, *American Druggist First Databank Annual Directory of Pharmaceuticals and Essential Directory of Pharmaceuticals*, commonly referred to as the Blue Book; (c) and Facts & Comparisons, Inc., a division of Lippincott Williams & Wilkins, Inc., a Pennsylvania corporation which acquired all drug information reference products formerly published by Medi-Span, Inc. and which currently makes available drug pricing information, including, but not limited to, the Medi-Span Master Drug Data Base. These entities are collectively referred to herein as "the Publishers."

#### **The Manufacturer-Publisher Enterprises**

173. For purposes of this claim, the "Manufacturer Publisher Enterprises" are associations-in-fact consisting of (a) the various Publishers that reported AWP's for Covered Drugs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents ("the

Manufacturer-Publisher Enterprises"). The Manufacturer-Publisher Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, and administering Covered Drugs to persons whose costs are reimbursed by Suffolk in accordance with Suffolk's obligations under federal and state Medicaid law, and deriving profits from these activities.

174. At all relevant times, each of the Publishers was aware of the defendants' drug AWP Scheme, was a knowing and willing participant in that scheme, profited from that scheme, and was aware of the involvement of other publishers in that scheme.

#### **The Medicaid Enterprise**

175. In the alternative, at all relevant times and in accordance with 18 U.S.C. §1961(4), an association-in-fact consisting of each of the federal and state agencies that act under federal and state Medicaid statutes, i.e., 42 U.S.C. § 1396 *et seq.* and N.Y. Soc. Serv. L. § 367 *et seq.* constituted a RICO "enterprise," referred to herein as "The Medicaid Enterprise." As alleged herein, each member of the Medicaid Enterprise paid reimbursements for Covered Drugs manufactured by the defendants, and each of these members was victimized by the AWP Scheme.

#### **The Publisher Enterprises**

176. In the alternative, at all times relevant herein the publishers identified in ¶ 172 herein each constituted a separate "enterprise" under 18 U.S.C. § 1961(4). The publishers of pharmaceutical industry compendia periodically publish AWP's, in printed and electronic media, for various dosages of drugs. As alleged herein, defendants participated in the operation of these enterprises' affairs concerning Covered Drugs.

### **Defendants' Use of the U.S. Mails and Interstate Wire Facilities**

177. The Manufacturer-Publisher Enterprises and the Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of Covered Drugs; and/or the transmission and/or receipt of sales pricing and marketing literature; and/or the transmission and/or receipt of invoices, statements, pricing data and payments related to the use or administration of Covered Drugs. During all relevant times, the Manufacturer-Publisher Enterprises and the Publisher Enterprises participated in the administration of Covered Drugs to thousands of individuals located throughout the United States. Similarly, during all relevant times, the activities of the Medicaid Enterprise engaged in and affected interstate commerce by establishing a statutory scheme whereby persons who purchased Covered Drugs manufactured and sold by the defendants were reimbursed for the administration of brand name prescription drug benefits based on AWP.

178. During the all relevant times, the defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

179. The nature and pervasiveness of the defendants' AWP Scheme, which was orchestrated out of the corporate headquarters of the defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the federal and state medicaid agencies, as well as various local district managers overseeing the

sales force, the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees, who communicated with the publishers.

180. Many of the precise dates of defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts) have been hidden and cannot be alleged without access to these defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

181. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the relevant time, including, *inter alia*:

- A. Marketing materials about the AWP's for Covered Drugs and the available spread, which were sent to providers located across the country;
- B. Written representations of the AWP's made to the Publishers, which were made at least annually and in many cases several times during a single year;
- C. Documents providing information or incentives designed to lessen the prices that providers paid for Covered Drugs and/or to conceal those prices or the AWP Scheme alleged here;
- D. Written communications, including checks, relating to rebates, kickbacks or other financial inducements as detailed herein;

E. Written and oral communications with U.S. and state Government agencies and private insurers that fraudulently misrepresented what the AWP's were, or that were intended to deter investigations into the true nature of the AWP's or to forestall changes to reimbursement based on something other than AWP's;

F. Written and oral communications with health insurers and patients, inducing payments for the drugs that were made in reliance on AWP's; and

G. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities -the wrongful proceeds of the defendants' AWP Scheme.

H. In addition to the above-referenced RICO predicate acts, the Publishers have distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities. Further, defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Complaint.

#### **Conduct of the RICO Enterprises' Affairs and RICO Conspiracy**

182. During all relevant times, each defendant has exerted control over their particular Manufacturer-Publisher Enterprise and Publisher Enterprises and, in violation of Section 1962(c) of RICO, has conducted or participated in the conduct of the affairs of that RICO enterprise, directly or indirectly, in the following ways:

A. Each Defendant Drug Manufacturer has directly controlled the price for its Covered Drugs;

B. Each Defendant Drug Manufacturer has directly controlled the AWP's that are reported by the Publishers;

C. Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers nationwide of the profit potential of its Covered Drugs;

D. Each Defendant Drug Manufacturer has relied upon its employees and agents to promote the AWP Scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and the Publishers;

E. Each Defendant Drug Manufacturer has controlled and participated in the affairs of its respective Manufacturer-Publisher Enterprise and Publisher Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs on the basis of AWP's that each Defendant Drug Manufacturer provides to the Publishers; and

F. The Publishers distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities.

183. Each of the Manufacturer-Publisher Enterprises identified in ¶ 169 of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

184. Each of the Publisher Enterprises identified in ¶ 172 had a hierarchal decision-making structure headed by the respective defendant. Each of the distribution enterprises also had a consensual decision-making structure because, as described above, the providers played an active role in the affairs of the enterprise.

185. In violation of Section 1962(c) of RICO, each of the defendants has conducted the affairs of each of the Manufacturer-Publisher Enterprises and Publisher Enterprises with which it associated by reporting fraudulently inflated AWP's for Covered Drugs that were then published by the Publishers, thereby inducing Suffolk, given its federal and state statutory obligations, to reimburse costs for covered drugs at inflated amounts.

**Pattern of Racketeering Activity**

186. Each of the defendants has conducted and participated in the affairs of the particular Manufacturer-Publisher Enterprises and Publisher Enterprises through a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. §1341, relating to mail fraud, and 18 U.S.C. §1343, relating to wire fraud. These patterns of racketeering likely involved thousands, if not hundreds-of-thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), in which the defendants intended to defraud Suffolk and other intended victims of the AWP Scheme.

187. The defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP's for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that manufacturer's Covered Drugs. Further, others would bill their clients for the defendants' Covered Drugs based on the inflated AWP's, which did not reflect the true price paid for the Covered Drugs.

188. The AWP Scheme was calculated and intentionally crafted so as to ensure that Plaintiff would reimburse for the drugs based upon falsely inflated AWPs. While designing and implementing this scheme, at all times these defendants were cognizant of the fact that Plaintiff was statutorily obligated to reimburse its Medicaid pharmacy costs based on the AWP as reported by the Publishers.

189. By intentionally and artificially inflating the AWPs, and by subsequently failing to disclose such practices to the individual patients and their insurers, the defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

190. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiff. Each separate use of the U.S. mails and/or interstate wire facilities employed by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff. Each of the defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Publisher Enterprise.

#### **Damages Caused Proximately By Defendants' AWP Scheme**

191. The defendants' violations of federal, state and common law and their pattern of racketeering activity have directly and proximately caused Plaintiff to be injured because Plaintiff has paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.

192. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWPs and other information by the same methods in furtherance of their AWP



Scheme. Plaintiff has made inflated reimbursements or payments for Covered Drugs based on and/or in reliance on reported and false AWP.

193. Under the provisions of Section 1964(c) of RICO, defendants are jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

### **COUNT III**

#### **VIOLATIONS OF 18 U.S.C. § 1962(a)**

194. Plaintiff incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint.

195. Throughout all relevant times, defendants have violated the federal RICO statute 18 U.S.C. § 1962(a) by using and investing income that was received from a pattern of racketeering activity as herein discussed to acquire an interest in, to establish, or to operate a variety of enterprises engaged in and affecting interstate commerce.

#### **The Distribution Enterprises**

196. The enterprises are the Distribution Enterprises identified in ¶ 145 herein.

197. In accordance with 18 U.S.C. § 1961(4), the Distribution Enterprises enumerated are associations-in-fact consisting of (a) various and independent medical providers who prescribed Covered Drugs, and (b), each individual Defendant Drug Manufacturer, including its directors, employees and agents ("The Distribution Enterprises"). The Distribution Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, prescribing, and

administering Covered Drugs to persons reimbursed by Suffolk in accordance with Suffolk's obligations under federal and state Medicaid, law, and deriving profits from these activities.

### **The Manufacturer Enterprises**

198. In the alternative, each Defendant Drug Manufacturer was itself and "enterprise" within the meaning of 18 USC §1961 (4). These enterprises are collectively referred to as the "Manufacturer Enterprises."

### **Defendants' Use of the U.S. Mails and Interstate Wire Facilities**

199. At all relevant times, the Distribution Enterprises and the Manufacturer Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale and/or purchase of Covered Drugs, and/or the transmission of sales and marketing literature, and/or the transmission and/or receipt of invoices and payments related to the use of Covered Drugs. During all relevant times, the Distribution Enterprises prescribed and/or administered Covered Drugs to thousands of individuals located throughout the United States.

200. The defendants' fraudulent and wrongful practices, illegal conduct, and violations of RICO were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and interstate wire facilities.

201. The nature and pervasiveness of the defendants' AWP Scheme, which was orchestrated from the defendants' corporate headquarters, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and interstate wire facilities with various local

district managers who oversee the sales forces and the numerous pharmaceutical sales representatives who, in turn, directly communicated with the providers.

202. Many of the precise dates of the defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and, as alleged above, the defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme to defraud and do so below.

203. The defendants' use of the U.S. mails and interstate wire facilities to perpetrate their AWP Schemes involved thousands of communications throughout the relevant time including, *inter alia*:

- A. Marketing materials about the AWP's for Covered Drugs and the available spread, which were sent to providers located across the country;
- B. Written representations of the AWP's for Covered Drugs made to the *Red Book* and similar publications, which were made at least annually, and in many cases, several times during a single year;
- C. Thousands of written and oral communications discussing, confirming, and forwarding free samples of drugs, for which the defendants understood that the providers would unlawfully seek inflated reimbursement.

D. Documents providing information or incentives designed to lessen the prices that providers paid for the drugs, and/or to conceal those prices or the AWP Scheme alleged here;

E. Written communications, including checks, documents discussing and relating to grants, payments of consulting fees, debt forgiveness and/or other financial inducements, as detailed herein;

F. Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWP's for Covered Drugs were, or that were intended to deter investigations into the AWP's for the Covered Drugs or to forestall changes to reimbursement based on something other than AWP's;

G. Written and oral communications with health insurers and patients, inducing payments for Covered Drugs that were made in reliance on AWP's; and

H. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities -the wrongful proceeds of the defendants' AWP Scheme.

I. In addition to the above-referenced RICO predicate acts, the defendants' respective corporate headquarters have communicated by use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Complaint.

#### **Conduct of the RICO Enterprises' Affairs and RICO Conspiracy**

204. During all relevant times, each defendant has used or invested, directly or indirectly, income derived from a pattern of racketeering activity to acquire an interest in, to establish

or to operate its particular Distribution Enterprise in violation of Section 1962(a) of RICO, in the following ways:

- A. Each defendant has directly controlled the price at which providers purchase its Covered Drugs;
- B. Each defendant has directly controlled the AWP's that are reported in the *Red Book* and similar industry publications;
- C. Each defendant has directly controlled the price at which providers are reimbursed by the Medicaid Program;
- D. Each defendant has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers located nationwide of the profit potential of its Covered Drugs;
- E. Each defendant has directly controlled the marketing and sales scheme to artificially and unlawfully inflate the Medicaid reimbursement rate (and co-payment rate) to induce providers to prescribe Covered Drugs to their patients;
- F. Each defendant has directly controlled the use and distribution of free samples of its Covered Drugs to providers;
- G. Each defendant has directly or indirectly controlled the ability of providers to unlawfully seek reimbursement from the Medicaid Program for free samples;
- H. Each defendant has relied upon its employees and agents to promote the AWP Schemes alleged herein through the U.S. mails, through interstate wire facilities, and through direct contacts with providers; and

I. Each defendant has controlled and participated in the affairs of its respective Distribution Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs through the use of unlawful inducements to providers.

205. Each of the Distribution Enterprises identified in ¶ 144 of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer. Each of the distribution enterprises also had a consensual decision-making structure because, as described above, the providers played an active role in the affairs of the enterprise. In violation of Section 1962(d) of RICO, each of the defendants and each of the providers that were members of the Distribution Enterprises conspired to conduct the affairs of such enterprises through the pattern of racketeering activity alleged herein. The conspiratorial agreement between the defendants and the providers and their overt acts are described in this Complaint.

206. In violation of Section 1962(a) of RICO, each of the defendants have used or invested income they received from a pattern of racketeering activity to acquire an interest in, to establish, or to operate the Medicaid Enterprise with which they dealt by reporting fraudulently inflated AWP's for Covered Drugs, thereby inducing Suffolk, given its statutory obligation to reimburse purchases at inflated amounts for Covered Drugs.

#### **Pattern of Racketeering Activity**

207. Each of the defendants has used or invested income received from a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1343, relating to wire fraud, to acquire an interest in, to establish, or to operate its respective Distribution Enterprises and the Manufacturer Enterprises. The defendants' pattern of

rackeering likely involved thousands, if not hundreds-of-thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes a "rackeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively, these violations constitute a "pattern of rackeering activity" within the meaning of 18 U.S.C. §1961(5) in which the defendants intended to defraud Plaintiff and other intended victims of the AWP Scheme.

208. The defendants' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP's for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce providers to prescribe their Covered Drugs to their patients and causing the Medicaid program to pay an artificially-inflated rate of reimbursement for the Covered Drugs. The defendants' AWP Scheme also consisted of providing free samples of the drugs to providers, instructing (or urging) such providers to bill the Medicaid program for these free samples, and providing the providers with other unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs.

209. The AWP Scheme was calculated and intentionally crafted so as to ensure that the Medicaid Program would be over-billed for the Covered Drugs. In designing and implementing the AWP Scheme, the defendants were at all cognizant of the fact that the entire Medicaid Program and all patients for whom the Covered Drugs are prescribed rely upon the honesty of the defendants in setting the AWP as reported in the *Red Book* and similar publications. Thus, Plaintiff was a foreseeable and intended target of the defendants' AWP Scheme.

210. By intentionally and artificially inflating the AWP and thereby affording providers unlawful financial inducements to use the Covered Drugs, and by subsequently failing to disclose such practices to the patients from whom reimbursement was sought through the U.S. mails or interstate wire facilities, the defendants engaged in fraudulent, and unlawful conduct constituting a pattern of racketeering activity.

211. The defendants' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive Plaintiff. Each separate use of the U.S. mails and/or interstate wire facilities employed by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff. Each of the defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Distribution Enterprise and the Medicaid Enterprises.

**Damages Proximately Caused By the Defendants' AWP Scheme**

212. The defendants' violations of federal, state and common law and their pattern of racketeering activity have directly and proximately caused Plaintiff to be injured because Plaintiff has paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.

213. Under the provisions of Section 1964(c) of RICO, defendants are jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.



#### COUNT IV

##### **VIOLATIONS OF 18 U.S.C. §1962(a)**

214. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

215. Throughout relevant times, defendants have violated the federal RICO statute by using and investing income that was received from a pattern of racketeering activity as alleged herein, to acquire, establish, and/or operate a variety of enterprises engaged in and affecting interstate commerce.

216. The RICO "enterprises" are the Manufacturer-Publisher Enterprises and the Publisher Enterprises identified in ¶¶ 169-70, 172 herein. As alleged herein, defendants acquired an interest in, or established, or operated these enterprises by using income received from a pattern of racketeering activity as alleged herein.

##### **The Manufacturer-Publisher Enterprises**

217. For purposes of this claim, the "Manufacturer Publisher Enterprises" are associations-in-fact consisting of (a) the various Publishers that reported AWP's for Covered Drugs, and (b) a Defendant Drug Manufacturer, including its directors, employees and agents ("the Manufacturer-Publisher Enterprises"). The Manufacturer-Publisher Enterprises are ongoing and continuing business organizations consisting of both corporations and individuals that are and have been associated for the common purposes of selling, purchasing, and administering Covered Drugs to persons reimbursed by Plaintiff and deriving profits from these activities.

218. At all relevant times, each of the publishers was aware of the defendants' drug AWP Scheme, was a knowing and willing participant in that scheme, profited from that scheme, and was aware of the involvement of other publishers in that scheme.

#### **The Publisher Enterprises**

219. In the alternative, at all times relevant herein the publishers identified in ¶ 172 herein each constituted a separate "enterprise" under 18 U.S.C. ¶ 1961(4). The publishers of pharmaceutical industry compendia periodically publish AWP's, in printed and electronic media, for various dosages of drugs. As alleged herein, defendants used income received from racketeering activity to acquire an interest in, to establish, or to operate these enterprises.

#### **Defendants' Use of the U.S. Mails and Interstate Wire Facilities**

220. The Manufacturer-Publisher Enterprises and the Publisher Enterprises engaged in and affected interstate commerce because they engage in the following activities across state boundaries: The sale, purchase and/or administration of Covered Drugs; and/or the transmission and/or receipt of sales pricing and marketing literature; and/or the transmission and/or receipt of invoices, statements, pricing data and payments related to the use or administration of Covered Drugs. During all relevant times, the Manufacturer-Publisher Enterprises and the Publisher Enterprises participated in the administration of Covered Drugs to thousands of individuals located throughout the United States.

221. During all relevant times, the defendants' illegal conduct and wrongful practices were carried out by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products and funds by the U.S. mails and

interstate wire facilities. Similarly, during all relevant times, the activities of the Medicaid Enterprise engaged in and affected interstate commerce by establishing a statutory scheme whereby persons who purchased Covered Drugs manufactured and sold by the defendants were reimbursed for the administration of brand name prescription drug benefits based on AWP's.

222. The nature and pervasiveness of the defendants AWP Scheme, which was orchestrated out of the corporate headquarters of the defendants, necessarily required those headquarters to communicate directly and frequently by the U.S. mails and by interstate wire facilities with the federal and state medicaid agencies, as well as various local district managers overseeing the sales force, the numerous pharmaceutical sales representatives who, in turn, directly communicated with providers and employees, who communicated with the publishers.

223. Many of the precise dates of defendants' uses of the U.S. mails and interstate wire facilities (and corresponding RICO predicate acts) have been hidden and cannot be alleged without access to these defendants' books and records. Indeed, an essential part of the successful operation of the AWP Scheme alleged herein depended upon secrecy, and as alleged above, the defendants took deliberate steps to conceal their wrongdoing. However, Plaintiff can generally describe the occasions on which the RICO predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the AWP Scheme and do so below.

224. Defendants' use of the U.S. mails and interstate wire facilities to perpetrate the AWP Scheme involved thousands of communications throughout the relevant time, including, *inter alia*:

- A. Marketing materials about the AWP's for Covered Drugs and the available spread, which were sent to providers located across the country;
- B. Written representations of the AWP's made to the Publishers, which were made at least annually and in many cases several times during a single year;
- C. Documents providing information or incentives designed to lessen the prices that providers paid for Covered Drugs and/or to conceal those prices or the AWP Scheme alleged here;
- D. Written communications, including checks, relating to rebates, kickbacks or other financial inducements as detailed herein;
- E. Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWP's were, or that were intended to deter investigations into the true nature of the AWP's or to forestall changes to reimbursement based on something other than AWP's;
- F. Written and oral communications with health insurers and patients, inducing payments for the drugs that were made in reliance on AWP's; and
- G. Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities -the wrongful proceeds of the defendants' AWP Scheme.
- H. In addition to the above-referenced RICO predicate acts, the Publishers have distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities. Further, defendants' corporate headquarters have communicated through use of the U.S.

mails and by interstate wire facilities with their various local headquarters or divisions in furtherance of the AWP Scheme. These mails include some of the documents referenced in this Complaint.

**Conduct of the RICO Enterprises' Affairs and RICO Conspiracy**

225. During all relevant times, the defendants have used or invested income received from a pattern of racketeering activity to acquire an interest in, to establish, or to operate their particular Manufacturer-Publisher Enterprise and Publisher Enterprises in violation of Section 1962(a) of RICO, in the following ways:

- A. Each Defendant Drug Manufacturer has directly controlled the price for its Covered Drugs;
- B. Each Defendant Drug Manufacturer has directly controlled the AWP's that are reported by the Publishers;
- C. Each Defendant Drug Manufacturer has directly controlled the creation and distribution of marketing, sales, and other materials used to inform providers nationwide of the profit potential of its Covered Drugs;
- D. Each Defendant Drug Manufacturer has relied upon its employees and agents to promote the AWP Scheme through the U.S. mails, through interstate wire facilities, and through direct contacts with providers and the Publishers;
- E. Each Defendant Drug Manufacturer has controlled and participated in the affairs of its respective Manufacturer-Publisher Enterprise and Publisher Enterprise by using a fraudulent scheme to manufacture, market and sell its Covered Drugs on the basis of AWP's that each Defendant Drug Manufacturer provides to the Publishers; and

F. The Publishers distributed their publications containing false AWP's through the U.S. mails and by interstate wire facilities.

226. Each of the Manufacturer-Publisher Enterprises identified in ¶¶ 169-170 of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

227. Each of the Publisher Enterprises identified in ¶ 172 of this Complaint had a hierarchical decision-making structure headed by the respective Defendant Drug Manufacturer.

228. In violation of Section 1962(c) of RICO, each of the defendants has used or invested income received from a pattern of racketeering activity to acquire an interest in, to establish, or to operate of each of the Manufacturer-Publisher Enterprises and Publisher Enterprises with which it associated by reporting fraudulently inflated AWP's for Covered Drugs that were then published by the Publishers.

#### **Pattern of Racketeering Activity**

229. Each of the defendants has acquired interest in, or established, or operated the particular Manufacturer-Publisher Enterprises and Publisher Enterprises by using or investing income received from a pattern of racketeering activity, including acts that are indictable under 18 U.S.C. §1341, relating to mail fraud, and 18 U.S.C. §1343, relating to wire fraud. These defendants' patterns of racketeering likely involved thousands, if not hundreds-of-thousands, of separate instances of use of the U.S. mails or interstate wire facilities in furtherance of their AWP Scheme. Each of these fraudulent mailings and interstate wire transmissions constitutes "racketeering activity" within the meaning of 18 U.S.C. §1961(1). Collectively, these violations constitute a "pattern of racketeering

activity," within the meaning of 18 U.S.C. § 1961(5), in which the defendants intended to defraud Suffolk and other intended victims of the AWP Scheme.

230. The defendants Drug Manufacturers' fraudulent and unlawful AWP Scheme consisted, in part, of deliberately overstating the AWP's for their Covered Drugs, thereby creating a "spread" based on the inflated figure in order to induce others to advocate and favor that manufacturer's Covered Drugs. Further, others would bill their clients for the defendants' Covered Drugs based on the inflated AWP's, which did not reflect the true price paid for the Covered Drugs.

231. The AWP Scheme was calculated and intentionally crafted so as to ensure that Plaintiff would reimburse for the drugs based upon falsely inflated AWP's. While designing and implementing this scheme, at all times these defendants were cognizant of the fact that Plaintiff was statutorily obligated to reimburse its Medicaid pharmacy costs based on the AWP as reported by the Publishers.

232. By intentionally and artificially inflating the AWP's, and by subsequently failing to disclose such practices to the individual patients and their insurers, the defendants engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

233. Defendants' racketeering activities amounted to a common course of conduct, with similar pattern and purpose, intended to deceive Plaintiff. Each separate use of the U.S. mails and/or interstate wire facilities employed by the defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including Plaintiff. Each of the defendants has engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its particular Publisher Enterprise.

### **Damages Proximately Caused By the Defendants' AWP Scheme**

234. The defendants' violations of federal, state and common law and their pattern of racketeering activity have directly, proximately and foreseeably caused Plaintiff to be injured because Plaintiff has paid many millions of dollars in inflated reimbursements or other payments for Covered Drugs.

235. Defendants sent billing statements through the U.S. mails or by interstate wire facilities and reported AWP's and other information by the same methods in furtherance of their AWP Scheme. Plaintiff has made inflated reimbursements or payments for Covered Drugs based on and/or in reliance on reported and false AWP's.

236. Under the provisions of Section 1964(c) of RICO, defendants are jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

### **COUNT V**

#### **MEDICAID FRAUD**

#### **42 U.S.C. § 1396r-8 and N.Y. Soc. Serv. Law § 367(A)(7)(d)**

237. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.

238. Each of the Defendant pharmaceutical companies is a manufacturer of a Covered Drug.

239. Pursuant to 42 U.S.C. § 1396r-8, each of the Defendant pharmaceutical companies entered into a rebate agreement with the Medicaid Program under which the Medicaid



Program would receive rebates determined in part by "best price," which is defined as "the lowest price available from the manufacturer."

240. In particular, as part of the rebate agreement, each Defendant agreed that:

(a) It would determine its best price, taking into account discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and would make quarterly rebates where necessary to bring the price down to the actual lowest price offered to any commercial entity;

(b) It would also determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

(c) It would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of a product at a nominal price was not contingent on any other sale.

241. 42 U.S.C. § 1396r-8 is incorporated by New York State's Medicaid Statute.

See New York Social Services Law § 367-(a)(7)(d). New York law expressly provides that each of the defendants who have executed a rebate agreement are to be paid pursuant to that agreement.

242. After execution of its agreement, each Defendant reported its "best price" in each quarter to the Medicaid Program.

243. In keeping with their artificial price inflation scheme, each Defendant did not report the actual "best price" or "average manufacturer's price," but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians that resulted in lower prices than the prices reported to the Medicaid Program.

244. Each of the defendants thereby violated 42 U.S.C. § 1396r-8 and N.Y.Soc. Serv. Law § 367-(a)(7)(d) in that they submitted untrue, incomplete, inaccurate, and misleading information used to determine the amount of reimbursement under the Medicaid program. More specifically, each Defendant made or caused claims to be made to the effect that the Medicaid Program was not receiving rebates based upon accurately reported "best price" information, knowing the claims to be rendered false, in whole or in part, falsely reported the prices paid by commercial entities for its products and not accounting for the discounts and other inducements offered to commercial entities. Further, acting with the intent to defraud and in order to obtain authorization to qualify as a provider and to provide specific goods, each Defendant made or caused to be made false statements promising that it would comply with the mandates of 42 U.S.C. § 1396r-8.

245. Defendants knew, or by virtue of their position, authority or responsibility should have known, of the falsity of their claims, statements or representations.

246. Defendants had the authority or responsibility to make such claims, statements and representations, exercised that authority and, as a direct or indirect result, the false statement was made, resulting in a claim for an item when defendants knew or had reason to know that they were not entitled under applicable statutes, regulations, rules, or policies to Medicaid payment or for the amount of payment requested or claimed.

247. As a result of the defendants' violations of 42 U.S.C. § 1396r-8 and New York Social Services Law § 367 *et seq.*, Suffolk paid substantially higher prices for reimbursement of the Covered Drugs than it should have, and the Medicaid Program was deprived of its appropriate rebate as a result of defendants' inaccurate reporting of best price.

## COUNT VI

### BREACH OF CONTRACT

248. The County of Suffolk realleges and incorporates by reference ¶¶1-144, 239-243, 246-247 as if fully set forth herein.

249. As required by 42 U.S.C. § 1396r-8, each Defendant entered into a Rebate Agreement with the Secretary of Health and Human Services ("HHS"). In that agreement, each agreed to comply with Section 1396r-8, and hence:

(a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary; and

(b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid;" and

(c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

250. New York Social Services Law § 367-(a)(7)(D) expressly states that any defendant who has entered into such rebate agreement with HHS, is to be reimbursed pursuant to 42 U.S.C. § 1396r-8.

251. Suffolk, like any Medicaid payor, was an intended third-party beneficiary of these rebate agreements.

252. After execution of the rebate agreements, defendants reported their average manufacturer's price in each quarter to the Medicaid Program.

253. In keeping with their artificial inflation of the AWP's, defendants did not report the actual "best price," for, but not limited to, the drugs identified herein but a significantly greater price that, among other things, excluded discounts and other inducements offered to physicians.

254. Defendants have therefore breached their rebate agreements and caused massive foreseeable damage to the County of Suffolk.

## **COUNT VII**

### **UNFAIR TRADE PRACTICES**

**(Violations of N.Y. Genl. Bus. Law § 349 *et seq.*)**

255. The County of Suffolk realleges and incorporates by reference ¶¶1-142, 239-243, 246-247 as if fully set forth herein.

256. Defendants herein have intentionally and wrongfully inflated the reporting of Average Wholesale Prices for the Covered Drugs.

257. As alleged herein, this AWP scheme was designed to increase defendants' sales for their drugs, control the market and decrease consumer choice.

258. Defendants intentional wrongful acts caused direct damage to tax paying consumers and Suffolk by wrongfully increasing their Medicaid burden.

259. The defendants intentional misconduct has damaged the public and Suffolk County taxpayers.

260. New York's Medicaid Statute expressly states, *inter alia*, that "[m]edical assistance for needy persons is hereby declared to be a matter of public concern and a necessity in promoting the public health and welfare." See Social Services Law § 363. Defendants' deceptive acts, as described herein, are in direct contravention of this statutorily articulated public policy. Defendants' practices were consumer-oriented and continue to have a broad impact on consumers and the taxpaying public.

261. The County is required by State Law to balance its budget. Every dollar spent on Medicaid, is a dollar that cannot be spent elsewhere.

262. Defendants' conduct as alleged in this Complaint constitutes deceptive acts or practices in that:

A. Defendants have failed to disclose material facts in the conduct of trade or commerce in that they have not disclosed that the AWP does not reflect the true average wholesale price of the drug products they sell, and that the "best prices" they report are not the actual "best prices" offered to other commercial entities, but are instead inflated in order to drive up the prices paid for medications by the County of Suffolk;

B. Defendants have made false or misleading statements of facts concerning the price of goods in that they have lied about the true AWP and "best prices" paid for their medications in order to drive up the prices paid by the County of Suffolk;

C. Defendants have knowingly made false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs,

and that their reported "best prices" are in fact the "best prices" offered to a commercial entity for their drugs; and

D. Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the "best price" requirement of the Medicaid statute, the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343, the Racketeer Influenced and Corrupt Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) and (d), and New York's Social Services Law, § 367-a, *et seq.* These statutory violations serve, at minimum, as predicates for the violation of New York's Gen. Bus. Law §349.

263. The wrongful conduct alleged in this Complaint occurs and continues to occur in the ordinary course of defendants' business and has caused great harm to the County of Suffolk and the consumers who live there. Suffolk has suffered actual damages because it has had to overpay millions of dollars in Medicaid pharmacy costs as a direct and proximate result of defendants' deceptive practices.

## **COUNT VIII**

### **FRAUD**

264. The County of Suffolk realleges and incorporates the preceding paragraphs as if fully set forth herein.

265. As detailed in this Complaint, defendants have engaged in actual fraud and have acted intentionally and with actual malice.

266. Defendants have made false representations with knowledge of their falsity, have concealed material facts with the purpose of overcharging Suffolk and Suffolk rightfully has

relied upon such misrepresentations. Direct, proximate and foreseeably injury has resulted as a result of such reliance.

267. Defendants also had knowledge of facts or intentionally disregarded facts that created a high probability of injury to Suffolk participants, and deliberately proceeded to act in conscious or intentional disregard of, or with indifference to, the high probability of this injury.

268. New York's Social Service Law § 366-b expressly provides that "any person who, with intent to defraud, presents for allowance or payment any false or fraudulent claim for furnishing services or merchandise, or who knowingly submits false information for the purpose of obtaining greater compensation than that to which he is legally entitled for furnishing services or merchandise, or knowingly submits false information for the purpose of obtaining authorization of furnishing services or merchandise under this title, shall be guilty of a class A misdemeanor...".

269. Defendants' knowing and intentional submission of inflated AWP's to publishers for the express purpose of effectuating the AWP scheme alleged herein constitutes an intentional fraud pursuant to common law and New York Social Services Law §366-b.

## **COUNT IX**

### **UNJUST ENRICHMENT**

270. The County of Suffolk realleges and incorporates by reference ¶¶1-142, 239-243, 246-247 as if fully set forth herein. As a direct and proximate result of the unlawful conduct described above, defendants have been and will continue to be unjustly enriched.

271. Defendants have benefitted from their unlawful acts through the increased sale of Covered Drugs with the greatest spread. It would be inequitable for defendants to retain any of

their ill-gotten gains earned as a result of the scheme alleged herein, which gains would not exist but for the overpayments made by Suffolk.

272. Suffolk is entitled to an accounting and the establishment of a constructive trust consisting of all overcharges paid by Suffolk for Covered Drugs.



### PRAYER FOR RELIEF

WHEREFORE, plaintiff the County of Suffolk prays for judgment against all defendants as follows:

1. Awarding plaintiff actual, statutory, treble and all other available damages for defendants' violation of 18 U.S.C. § 1962(c)-(d);
2. Awarding plaintiff actual, statutory, treble and all other available damages for defendants' violation of 18 U.S.C. § 1962(a);
3. Adjudging and decreeing that defendants have engaged in the intentional fraudulent conduct alleged herein in violation of N.Y. Soc. Serv. Law §§ 367(a)(7)(d), 366-b and 42 U.S.C. § 1396r-8;
4. Awarding Suffolk actual, statutory, treble and all other available money damages including interest for defendants' violation of N.Y. Gen. Bus. Law § 349 in an amount to be determined at trial;
5. Awarding Suffolk actual and compensatory damages in an amount to be determined at trial for defendants' breach of contract;
6. Awarding Suffolk actual and punitive damages in an amount to be determined at trial for defendants' intentional fraud;
7. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at Suffolk's expense, and disgorgement to Suffolk of such monies;
8. Imposing a constructive trust and ordering defendants to pay restitution to Suffolk in the amount Suffolk has been overcharged for Covered Drugs;
9. Awarding plaintiff the costs of the suit, including costs, reasonable attorneys' and experts' fees pursuant to 18 U.S.C. § 1964(c), and N.Y. Gen. Bus. Law § 349;
10. Such other further and different relief as the Court deems just and proper.

Dated: January 14, 2003.

KIRBY McINERNEY & SQUIRE, LLP

By: 

Roger W. Kirby  
Joanne M. Cicala  
Mark Booker

830 Third Avenue  
New York, New York 10022  
(212) 371-6600

COUNSEL FOR THE COUNTY OF SUFFOLK

**EXHIBIT A**  
**TOP 100 SUFFOLK COUNTY 2001 MEDICAID PHARMACY COSTS**

DRUG NAME/DOSAGE	DEFENDANT MANUFACTURER	% OF SUFFOLK'S PHARMACY COSTS
ZYPREXA TAB 10MG	ELI LILLY	4.32%
PROCRT INJ 40000U/M	ORTHO BIOTECH	1.75%
PRILOSEC CAP 20MG CR	ASTRAZENECA	1.68%
ZYPREXA TAB 5MG	ELI LILLY	1.63%
CLOZARIL TAB 100MG	NOVARTIS	1.40%
PREVACID CAP 30MG DR	TAP PHARM	1.37%
DEPAKOTE TAB 500MG EC	ABBOTT	1.32%
RISPERDAL TAB 2MG	JANSSEN	1.16%
CELEBREX CAP 200MG	SEARLE	0.99%
RISPERDAL TAB 3MG	JANSSEN	0.85%
ZYPREXA TAB 2.5MG	ELI LILLY	0.92%
PROZAC CAP 20MG	ELI LILLY	0.78%
RISPERDAL TAB 4MG	JANSSEN	0.76%
SYNAGIS INJ 100MG	MED IMMUNE	0.75%
NEURONTIN CAP 300MG	PARKE-DAVIS	0.74%
ZOLOFT TAB 50MG	PFIZER	0.72%
VIOXX TAB 25MG	MERCK	0.68%
ZOCOR TAB 20MG	MERCK	0.68%
AMBIEN TAB 10MG	SEARLE	0.66%
LIPITOR TAB 10MG	PARKE-DAVIS	0.62%
KALETRA CAP	ABBOTT	0.38%
DURAGESIC DIS 100MCG/H	JANSSEN	0.35%
LEVAQUIN TAB 500MG	McNEIL	0.35%
EPIVIR TAB 150MG	GLAXO	0.35%
RISPERDAL TAB 0.5MG	JANSSEN	0.34%
WELLBUTRIN TAB 150MG SP	GLAXO	0.34%
GLUCOPHAGE TAB 500MG	BRISTOL-MYERS SQUIBB	0.31%
PROCRT INJ 10000ML	ORTHO BIOTECH	0.31%
ZYPREXA TAB 20MG	ELI LILLY	0.31%
ZYRTEC TAB 10MG	PFIZER	0.30%
CRIVAN CAP 400MG	ELI LILLY	0.31%
PRAVACHOL TAB 40MG	BRISTOL-MYERS SQUIBB	0.29%
NORVASC TAB 5MG	PFIZER	0.29%
SUSTIVA CAP 200MG	BRISTOL-MYERS SQUIBB	0.29%
ENBREL INJ 25MG	IMMUNEX	0.29%
ALBUTEROL AER 90MCG <sup>4</sup>	VARIOUS	0.26%
SEROQUEL TAB 25MG	ASTRAZENECA	0.26%
PRAVACHOL TAB 20MG	BRISTOL-MYERS SQUIBB	0.27%
CIPRO TAB 500MG	BAYER	0.27%
SINGULAIR TAB 10MG	SCHEN	0.26%

<sup>4</sup> These two drugs have an established IICFA upper limit and may not be affected by the AWP scheme alleged herein.

SEREVENT AER 21MG	GLAXO	0.25%
BETASERON INJ 0.3MG	BERLEX	0.26%
PREVACID CAP 15MG DR	TAP PHARM	0.25%
RISPERDAL TAB 0.25MG	JANSSEN	0.25%
TOPAMAX TAB 100MG	ORTHO-McNEIL	0.25%
PAXIL TAB 30MG	SK BEECHAM	0.25%
ZOCOR TAB 40MG	PFIZER	0.24%
NEURONTIN CAP 400MG	PARKE-DAVIS	0.24%
PRILOSEC CAP 20MG CR	ASTRAZENECA	0.24%
AUGMENTIN TAB 875MG <sup>4</sup>	SK BEECHAM	0.23%
NEURONTIN TAB 600MG	PARKE-DAVIS	0.23%
IMMUNE GLOBU INJ 10%		0.23%
FLONASE SPR 0.05%	ALLEN & HANBURYS	0.23%
PAXIL TAB 10MG	SK BEECHAM	0.23%
FLOVENT AER 110MCG/A	GLAXO WELLCOME	0.23%
ACIPHEX TAB 20MG	JANSSEN	0.22%
FLUOXETINE CAP 20MG	VARIOUS	0.22%
CELEBREX CAP 100MG	SEARLE	0.22%
GLUCOPHAGE TAB 1000MG	BRISTOL-MYERS SQUIBB	0.22%
PROGRAF CAP 1MG	FUJISAWA	0.22%
PROZAC CAP 40MG	ELI LILLY	0.21%
OXYCONTIN TAB 40MG CR	PURDUE PHARMA	0.21%
ZITHROMAX TAB 250MG	PFIZER USPG	0.21%
LIPITOR TAB 40MG	PARKE-DAVIS	0.21%
GLUCOTROL XL TAB 10MG	PFIZER USPG	0.21%
AVANDIA TAB 8MG	GSK PHARM	0.20%
ZIAGEN TAB 300mg	GLAXO WELLCOME	0.20%
XALATAN SOL 0.005%	PHARMACIA CORP.	0.20%
EPFEXOR XR CAP 75MG	WYETH-AYERST	0.20%
PAXIL TAB 40MG	SK BEECHAM	0.20%
PULMOZYME SOL 1MG/ML	GENENTECH	0.20%
ULTRAM TAB 50MG	ORTHO-McNEIL PHARM	0.20%
BUSPAR TAB 15MG	BRISTOL MYERS SQUIBB	0.20%
TOBI NEB 300/5ML	CHIRON CORP.	0.20%
NEXIUM CAP 40MG	ASTRA ZENECA	0.19%
LAMICTAL TAB 100MG	GLAXO WELLCOME	0.19%
PROTONIX TAB 40MG	WYETH-AYERST	0.19%
EPOGEN INJ 10000/ML	AMGEN INC.	0.19%
OXYCONTIN TAB 80MG	PURDUE PHARMA	0.19%
FOSAMAX TAB 70MG	MERCK	0.19%
PLAVIX TAB 75MG	SANOFI	0.19%
NORVASC TAB 5MG	PFIZER	0.19%
NEUPOGEN INJ 300ML	AMGEN INC.	0.18%

# EXHIBIT C

ORIGINAL

UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

COUNTY OF WESTCHESTER,

Plaintiff,

v.

ABBOTT LABORATORIES, INC., AGOURON  
PHARMACEUTICALS, INC., AMGEN, INC.,  
ASTRAZENECA PHARMACEUTICALS L.P.,  
ASTRAZENECA US, BARR LABORATORIES,  
INC., BAYER CORPORATION, BAYER  
PHARMACEUTICALS, BERLEX  
LABORATORIES, INC., BIOGEN, INC.,  
BOEHRINGER INGELHEIM CORPORATION,  
BRISTOL-MYERS SQUIBB COMPANY, ELI  
LILLY AND COMPANY, FOREST  
PHARMACEUTICALS, INC., FUJISAWA  
HEALTHCARE, LTD., GILEAD SCIENCES, INC.,  
GLAXO WELLCOME, P.L.C.,  
GLAXOSMITHKLINE PLC, IMMUNEX  
CORPORATION, IVAX CORPORATION, IVAX  
PHARMACEUTICALS, INC., JANSSEN  
PHARMACEUTICA PRODUCTS, LP, JOHNSON &  
JOHNSON, MEDIMMUNE, INC., MERCK & CO.,  
INC., NOVARTIS PHARMACEUTICALS  
CORPORATION, ORTHO BIOTECH PRODUCTS,  
LP, ORTHO MCNEIL PHARMACEUTICAL, INC.,  
PFIZER INC., PHARMACIA CORPORATION,  
SANOFI-SYNTHELABO, INC.,  
SCHERING-PLOUGH CORP.,  
SMITHKLINEBEECHAM P.L.C.,  
SMITHKLINEBEECHAM CORPORATION,  
TAKEDA CHEMICAL INDUSTRIES, LTD.,  
TAKEDA PHARMACEUTICALS NORTH  
AMERICA, INC., TAP PHARMACEUTICAL  
PRODUCTS, INC., WARRICK  
PHARMACEUTICALS LTD, WYETH, and DOES 1-  
100

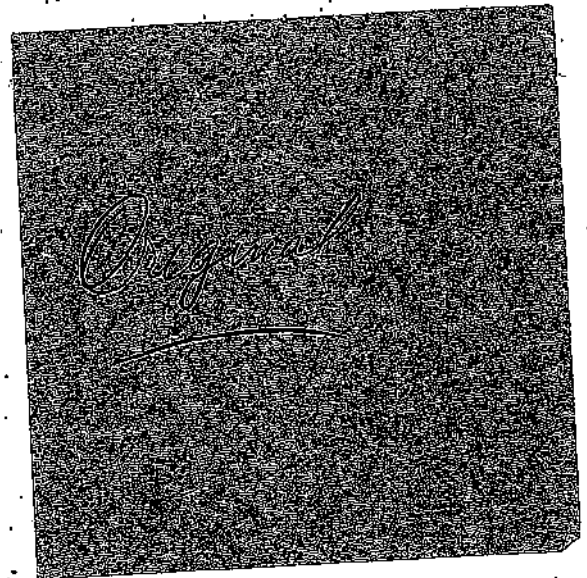
Defendants.

JUDGE McMAHON  
INDEX NO.

03 CV 6178

FILED  
U.S. DISTRICT COURT  
2002 AUG 13 PM 2:50

COMPLAINT



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Plaintiff, the County of Westchester (hereinafter "Westchester"), brings this action under the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, the Social Security Act, 42 U.S.C. § 1396r-8, New York Social Services Law §§367 and 145-b, New York General Business Law §349, and common law to recover monetary damages, civil penalties, declaratory and injunctive relief, restitution, disgorgement of profits, and treble and punitive damages suffered as a result of defendants' unlawful scheme to overcharge for prescription medications paid for by Medicaid. Westchester County is required by New York State law to pay 25% of its Medicaid costs, including the cost of prescription drugs ("pharmacy costs"). Westchester County is also required to balance its budget annually. Every dollar wrongfully spent on Medicaid could have properly been allotted to other public needs. Westchester's claims as to itself and its own actions are based upon its personal knowledge. All other allegations are based upon information and belief pursuant to the investigation of counsel.

## I. INTRODUCTION

1. Each of the defendants is or has been engaged in the business of manufacturing, marketing and selling prescription pharmaceuticals throughout the United States. The principal payors for such prescription pharmaceuticals are federal, state and local governments (under the Medicare and Medicaid Programs), private insurers and self-insured employers (Third-Party Payors), and private individuals (Patients). Plaintiff is a municipal corporation and local government required by New York State law to contribute 25% towards its Medicaid costs.

2. For the last decade, defendants have engaged in a systematic and pervasive fraudulent scheme with others in the pharmaceutical distribution chain, including but not limited to pharmacies, physicians, hospitals and other medical providers (hereinafter "providers"), to collect inflated prescription drug payments from Westchester. The scheme generally involves two types of wrongdoing, one of which impacts the other. First, the fraudulent reporting of false and inflated

average wholesale prices ("AWPs") (or wholesale acquisition costs ("WACs") on which AWP are based) for certain drugs. Second, the failure to report the "Best Price" for certain drugs in violation of federal and state Medicaid statutory requirements, which failure also inflates AWP.

3. It is standard practice that for federal Medicare and Medicaid Programs, state and local Medicaid entities (such as Westchester), Third Party Payors and patients reimburse providers for multi-source (generic) and brand name prescription drugs for which there is no "Federal Upper Limit" based upon the AWP for such drugs, as published and reported by third-party reporting services such as the Blue Book, Medispan or Red Book.

4. Westchester pays for most prescription drugs based on AWP pursuant to federal and state statute and regulation. Because defendants artificially inflate the AWP in order to manipulate reimbursements, plaintiff has made excessive payments. As set forth in Exhibit A hereto, defendants have reported false and inflated AWP for all Medicaid Covered Drugs paid for by Westchester. The improper inflation rates range up to 75%. This practice has resulted in millions of dollars in overcharges to Westchester County.

5. The inflationary scheme is successful in part because pharmaceutical companies either self-report an inflated AWP to publishers which then publish the AWP provided to them, or self-report an inflated WAC which the publisher then converts to AWP. In either case, the AWP is not independently determined by the publishers.

6. By federal and state statute and regulation, and industry practice, the AWP is intended and required to be based upon and directly related to actual prices paid by providers to pharmaceutical manufactures (or wholesalers) for such prescription drugs.

7. In fact, as has been revealed by Westchester's own investigation (See Exhibit A) and extensive and ongoing Congressional and federal investigations, and numerous recent

settlements involving many of the defendants herein, pharmaceutical manufacturers have engaged in a pervasive scheme, commencing in 1993 if not earlier, whereby they report or cause to be reported, fraudulent, fictitious and inflated AWP's or WAC's for certain prescription pharmaceuticals, including prescription pharmaceuticals paid for by Medicaid and thus by Westchester.

8. The fraudulent AWP Scheme described herein also has involved the affirmative failure of defendants to report their Best Prices as required by federal and state Medicaid statute, thereby further inflating the reported AWP's. Pursuant to 42 U.S.C. § 1396r-8, each of the defendants was required to report to the Secretary of Health and Human Services the lowest price it sold a drug to any for-profit entity. Each defendant agreed to offer the Medicaid Program its "best price." A like requirement appears in New York State's Medicaid Statute. See New York Social Services Law § 367-(a)(7)(d). Yet, defendants exclude from their reporting of best prices certain drugs offered at discounts or other rebates that would have reduced the price paid. They do so to avoid paying rebates to Medicaid and to avoid having to disclose the true best price, which would have required a reduction in the reported AWP.

9. The fraudulent reporting of Average Wholesale Prices and failure to report Best Price has the effect of materially misrepresenting and overstating the true AWP on which reimbursement should be based.

10. The motivation for the scheme is straight-forward. By inflating the AWP in which Medicaid reimbursement is based, defendants motivate providers to distribute the drugs with the highest reimbursement rate. This practice is known as "marketing the spread." Providers benefit by pocketing the difference between the reported AWP and the actual cost paid for the drug.

11. This scheme is not a matter of speculation. Defendant Bayer recently paid

\$260 million in civil and criminal fines in connection with allegations that they failed to report Best Prices for certain drugs thereby resulting in overcharges to Medicaid and Medicare. Defendant GlaxoSmithKline recently paid \$88 million to resolve civil charges that it caused Medicaid and Medicare to overpay for certain drugs. Defendant Abbott is paying \$621 million in criminal and civil penalties for defrauding Medicare and Medicaid and has affirmatively acknowledged its involvement in the fraud. Defendant Bristol-Myers is under investigation in connection with its pricing practices for drugs covered by Medicare and Medicaid. Defendant AstraZeneca paid \$355 million to settle federal fraud charges that it induced doctors to falsely bill Medicare and Medicaid. Defendant Pfizer paid \$49 million for failure to disclose discounts and properly report best prices for a certain drug. Defendant Schering-Plough faces threat of indictment for cheating the government out of Medicaid rebates and submitting false price information. Defendant TAP Pharmaceuticals paid \$875 million in connection with its fraudulent pricing practices respecting Lupron.

12. The foregoing settlements, the government investigations that prompted them, and the corporate integrity agreements executed by the settling companies are discussed herein. Certain of the settlements may impact a portion of Westchester's damages for certain years with respect to certain drugs. In any event, the settlements and compliance agreements executed by the settling parties confirm the allegations of wrongdoing herein.

13. Even as to the defendants not mentioned above, Westchester's initial research confirms that the practice of routinely and systematically inflating the reported AWP for certain drugs and failing to report Best Prices is pervasive. See Exhibit A. Indeed, defendants must participate lockstep in the fraud to prevent dispensers such as pharmacies and doctors from prescribing drugs of a competitor with a higher spread between Medicaid reimbursement rate and

retail price.

14. In brief summary, the fraudulent scheme devised and initiated by defendants and implemented by its co-conspirators (DOES 1-100) is effectuated by: (i) overstating the AWP for drugs for which Medicaid provides reimbursement based upon AWP ("Covered Drugs"); (ii) marketing and promoting the sale of Covered Drugs to providers based on the providers' ability to collect inflated payments from the government and Medicaid beneficiaries that exceeded payments possible for competing drugs; (iii) providing providers with unreported discounts, free samples and financial incentives to over-prescribe Covered Drugs or prescribe Covered Drugs in place of competing drugs; and (iv) overcharging the Medicaid program for illegally inflated Covered Drugs reimbursements.

15. According to one member of the Congressional Ways and Means Committee, describing the conduct of one defendant herein:

The price manipulation scheme is executed through Bristol's falsely inflated representations of average wholesale price ("AWP"), direct price ("DP"), and wholesale acquisition cost ("WAC"), which are utilized by the Medicare and Medicaid programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP, DP, and WAC versus the true price providers are paying, is regularly referred to . . . as "the spread."

\* \* \*

The evidence clearly shows that Bristol has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Bristol manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs where the arranging of a financial benefit or inducement would influence the decisions of healthcare providers submitting the Medicare and Medicaid claims.

(February 27, 2001 letter from Representative Pete Stark to Peter Dolar, President, Bristol-Myers Squibb Co.).

16. Westchester alleges upon information and belief that, in many instances, the AWP reported by the defendant pharmaceutical manufacturers bears a minimal relationship to the prices actually paid by providers and is "made up" by corporate pricing committees literally out of "thin air" for the purpose of manipulating pharmaceutical markets and increasing market share. Many of the facts underlying this fraud, such as the volume and nature of the discounts provided and free samples distributed, are peculiarly within defendants' control.

17. Thus, defendants knowingly have violated federal and state statutes by deliberately publishing false, inflated and misleading price data that directly results in excessive payments by Westchester. Neither federal nor state statutory schemes, even to the extent they base reimbursement on AWP, permit defendants to engage in this widespread, concerted fraud. Westchester would not have been damaged if defendants complied with the existing federal and state laws.

18. As a result of the fraudulent and illegal manipulation of AWP for covered drugs by defendants, defendants have reaped billions of dollars in illegal profits at the expense of American consumers, taxpayers and entities such as plaintiff that make pay reimbursements for Medicaid pharmacy costs.

## II. JURISDICTION AND VENUE

19. This action is brought for and on behalf of the County of Westchester, pursuant to, *inter alia*, the Racketeering Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, New York's Social Services Law §§ 145-b and 367a, New York's Consumer Protection Statute, Gen. Bus. Law § 349, and for breach of contract, unjust enrichment, and common law fraud.

20. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because the action alleges violations of the Racketeer Influenced and Corrupt Organizations Act, 18



U.S.C. § 1961, *et seq.* and the Social Security Act, 42 U.S.C. § 1396 *et seq.* This Court has supplemental jurisdiction over plaintiff's state law claims pursuant to 28 U.S.C. § 1367.

21. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) because defendants do business and are qualified to do business in this District; certain acts giving rise to the claims asserted in this Complaint occurred within this District; and the illegal actions of defendants, as alleged in this Complaint, caused damage to plaintiff within this District.

### III. PARTIES

22. Plaintiff, the County of Westchester, New York is and was at all relevant times, a body corporate and politic organized and existing under the laws of the State of New York with its principal place of business located at the Westchester County, 148 Martine Avenue, White Plains, NY 10601.

23. Defendant Abbott Laboratories, Inc. ("Abbott") is a highly diversified Illinois corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott's principal place of business is at 100 Abbott Park Road, Abbott Park, Illinois, 60064-3500. Abbott conducts extensive business in the State of New York, including in the County of Westchester. Abbott manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Depakote®, Kaletra® and Flomax®.

24. Defendant Amgen, Inc. ("Amgen") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Amgen's principal place of business is One Amgen Drive, Thousand Oaks, California, 91320-1799. Amgen does extensive business in the State of New York, including in the County of Westchester. Amgen manufactures and/or sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as

Neuprogen®, Enbrel® and Epogen®.

25. Two AstraZeneca PLC subsidiaries, defendant AstraZeneca US and defendant AstraZeneca Pharmaceuticals L.P. (collectively referred to as "AstraZeneca") are Delaware corporations whose principal businesses are the development, manufacture and sale of health care products including pharmaceuticals. AstraZeneca's principal place of business is at 1800 Concord Pike, Wilmington, Delaware, 19850. AstraZeneca does extensive business in the State of New York, including in the County of Westchester. AstraZeneca manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Nexium®, Prilosec®, Seroquel® and Pulmicort®.

26. Defendant Barr Laboratories, Inc. ("Barr") is a specialty pharmaceutical company primarily engaged in the development, manufacture and marketing of generic and proprietary prescription pharmaceuticals. Its business address is 2 Quaker Road Box 2900 Pomona, NY 10970-0519. Barr conducts extensive business in the State of New York, including in the County of Westchester. Barr manufactures and/or sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Fluoxetine®.

27. Two wholly-owned subsidiaries of German Bayer AG, Defendant Bayer Corporation and Defendant Bayer Pharmaceuticals (collectively referred to as "Bayer") are located in the US. Defendant Bayer Corporation ("Bayer") is an Indiana corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Bayer Corporation's principal place of business is located at 100 Bayer Road, Pittsburgh PA. Bayer's pharmaceutical division is located at 400 Morgan Lane, West Haven, Connecticut. Bayer conducts extensive business in the State of New York, including in the County



of Westchester. Bayer is a wholly owned US subsidiary of a German corporation, Bayer AG. Bayer manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Cipro®.

28. Defendant Berlex Laboratories, Inc. ("Berlex") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Berlex's principal place of business is 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000. Berlex conducts extensive business in the State of New York, including in the County of Westchester. Berlex Laboratories manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Betaseron®.

29. Defendant Biogen, Inc. ("Biogen") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Biogen's principal place of business is 14 Cambridge Center, Cambridge, Massachusetts 02142. Biogen conducts extensive business in the State of New York, including in the County of Westchester. Biogen manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Avonex®.

30. Defendant Boehringer Ingelheim Corporation ("Boehringer") is the U.S. member of the Boehringer worldwide group of companies whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Boehringer's principal place of business is 900 Ridgefield Road, Ridgefield, Connecticut. Boehringer does extensive business in the State of New York, including in the County of Westchester. Boehringer manufactures and sells prescription drugs with false and inflated AWP's

that are paid for by Medicaid in Westchester County, including such medications as Viramune®.

31. Defendant Bristol-Myers Squibb Company ("Bristol-Myers") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products, including pharmaceuticals. Bristol-Myers's principal place of business is 345 Park Avenue, New York, New York. Bristol-Myers does extensive business in the State of New York, including in the County of Westchester. Bristol-Myers manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Sustiva®, Pravachol®, Plavix® and Zerit®.

32. Defendant Eli Lilly and Company ("Eli Lilly") is an Indiana corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Lilly does extensive business in the State of New York, including in the County of Westchester. Eli Lilly's principal place of business Lilly Corporate Center, Indianapolis, IN, 46285. Eli Lilly manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Zyprexa®, and Humulin®.

33. Defendant Forest Pharmaceuticals Inc. ("Forest") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Forest's principal place of business is 13600 Shoreline Drive, St. Louis, Missouri 63045. Forest conducts extensive business in the State of New York, including in the County of Westchester. Forest manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Celexa®.

34. Defendant Fujisawa Healthcare, Inc. ("Fujisawa") is a Delaware corporation

headquartered at Three Parkway North, Deerfield, IL, 60015. Fujisawa is a wholly-owned subsidiary of Fujisawa Pharmaceutical Co., Ltd., a Japanese corporation. Fujisawa conducts extensive business in the State of New York, including in the County of Westchester. Fujisawa manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Prograf®.

35. Defendant Gilead Sciences, Inc., ("Gilead") is a Delaware corporation whose principal business is the discovery, development, manufacture, and sale of pharmaceuticals. Gilead's principal place of business is 333 Lakeside Drive, Foster City, CA, 94404. Gilead conducts extensive business in the State of New York, including in the County of Westchester. Gilead manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Viread®.

36. The GSK Defendants. (a) Defendant GlaxoSmithKline P.L.C. ("GSK") is a research-based pharmaceutical and healthcare public limited company incorporated under the laws of England and Wales that is engaged in the creation and discovery, development, manufacture and marketing of pharmaceutical products, vaccines, over-the-counter medicines and health-related consumer products. Its corporate headquarters are located at 980 Great West Road, Brentford, Middlesex, EN, TW8 9, U.K. GSK's United States operational headquarters are at One Franklin Plaza, Philadelphia, PA 19102. GSK also does business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina. GSK does extensive business in the State of New York, including in the County of Westchester.

(b) GSK was created through the merger of defendant Glaxo Wellcome, P.L.C. ("Glaxo") and defendant SmithKlineBeecham P.L.C. ("SKB P.L.C."). Both Glaxo and SKB P.L.C. are now wholly-owned subsidiaries of GSK.

(c) SKB P.L.C. owned defendant SmithKline Beecham Corporation ("SKB"). SKB is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, 16th and Race Streets, Philadelphia, Pennsylvania. SKB is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals.

(d) Glaxo and SKB at certain times relevant to this complaint, conducted extensive business in the County of Westchester including the sale of the pharmaceuticals that are the subject of the AWP Scheme alleged herein.

(e) Glaxo is a North Carolina corporation with its principal place of business at 5 Moore Drive, P.O. Box 13398, Research Triangle Park, North Carolina.

(f) Defendants GSK, SKB P.L.C., SKB and Glaxo, collectively referred to herein as the "GSK Defendants," manufacture and/or sell prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County. Glaxo and GSK manufacture and or sell prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Epivir® and Wellbutrin®, Lamictal®, Serevent®, Paxil®, Augmentin®, Avandia®, Ziagen®, Flovent®, Flonase®, Advair®, Trizivir® and Combivir®.

37. Defendant Immunex Corporation ("Immunex") is a Washington State corporation, with its principal place of business at 51 University Street, Seattle, Washington, 98101-2918 that was acquired by Amgen in July 2002, and has been a wholly-owned subsidiary since this merger. Immunex does business in the State of New York, including the County of Westchester. Immunex manufactures prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including Enbrel® which is marketed and sold by Amgen

and Wyeth.

38. Defendant Ivax Corporation, the parent of defendant Ivax Pharmaceuticals Inc. (Collectively know as "Ivax"), is a Florida corporation engaged in the research, development, manufacture and marketing of pharmaceutical products. Both principal places of business are located at 4400 Biscayne Blvd., Miami, FL, 33137. Ivax manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Clozapine®.

39. The Johnson & Johnson Defendants. (a) Defendant Johnson & Johnson ("J&J") is a New Jersey corporation engaged in the manufacture and sale of a broad range of products in the healthcare field. Its principal place of business is One Johnson & Johnson Plaza, New Brunswick, NJ, 08933. Johnson & Johnson is the corporate parent of defendants Janssen Pharmaceutica Products, Ortho McNeil, Pharmaceuticals, Inc. and Ortho Biotech Products, LP and is responsible for the marketing and distribution of its subsidiaries' drugs, which have false and inflated AWP's as set forth herein. The four defendants are at times referred to collectively herein as "the J&J Defendants."

(b) Defendant Janssen Pharmaceutica Products, LP ("Janssen") is a New Jersey limited partnership whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Janssen's principal place of business is 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. Janssen is subsidiary of defendant Johnson and Johnson. Janssen conducts extensive business in the State of New York, including in the County of Westchester. Janssen manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Risperdal® and Aciphex®.

(c) Defendant Ortho McNeil Pharmaceutical, Inc. ("Ortho McNeil") is a highly diversified health care company incorporated in New Jersey whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Ortho McNeil's principal place of business is 1000 U.S. Route 202 South, Raritan, New Jersey 08869. Ortho McNeil conducts extensive business in the State of New York, including in the County of Westchester. Ortho McNeil manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Levaquin® and Topamax®.

(d) Defendant Ortho Biotech Products, LP ("Ortho Biotech") is a New Jersey Corporation and has been a wholly owned subsidiary of defendant Johnson and Johnson since its formation in 1990. Ortho Biotech's principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey. Ortho Biotech manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Procrit®.

40. Defendant MedImmune, Inc. ("MedImmune") is a Delaware corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. MedImmune conducts extensive business in the State of New York, including in the County of Westchester. MedImmune's principal place of business is 35 W. Watkins Mill Road, Gaithersburg, Maryland 20878. MedImmune manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Synagis®.

41. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation whose principal business is the development, manufacture and sale of health care products including



pharmaceuticals. Merck's principal place of business is One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889-0100. Merck conducts extensive business in the State of New York, including in the County of Westchester. Merck manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Vioxx®, Zocor®, Singulair®, Cozaar® and Fosamax®.

42. Defendant Novartis Pharmaceuticals Corporation ("Novartis") is a New Jersey Corporation with its main place of business at One Health Plaza, East Hanover, New Jersey. Novartis is a U.S. affiliate of Novartis AG. Novartis is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Novartis conducts extensive business in the State of New York, including in the County of Westchester. Novartis manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Clozaril®.

43. The Pfizer Defendants.

(a) Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Pfizer's principal place of business is 235 East 42nd Street, New York, New York 10017. Pfizer does extensive business in the State of New York, including in the County of Westchester. Pfizer manufactures and/or sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Ambien®, Lipitor®, Neurontin®, Norvasc®, Zoloft®, Zyrtec®.

(b) Defendant Pharmacia Corporation ("Pharmacia"), which became a wholly owned subsidiary of Pfizer on April 16, 2003, is a Delaware corporation with its principal

place of business located at 100 Route 206, North Peapack, New Jersey. Pharmacia was created through the merger of defendant Pharmacia and Upjohn, Inc. and Monsanto Company on March 31, 2000. Pharmacia is a highly diversified health care company whose business includes the manufacture and sale of prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Celebrex® and Xalatan®.

(c) Defendant Sanofi-Synthelabo, Inc. ("Sanofi") is a highly diversified health care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Sanofi is included as a Pfizer Defendant because of its joint venture with Pharmacia (formerly Searle) to market Ambien®. Sanofi's principal place of business is One Well Street, New York, New York 10286. Sanofi conducts extensive business in the State of New York, including in the County of Westchester. Sanofi manufactures and /or sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Ambien®.

(d) Defendant Agouron Pharmaceuticals Inc. ("Agouron") is a California corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals and a wholly owned subsidiary of Pfizer. Agouron's principal place of business is 10350 North Torrey Pines Road, Suite 100 La Jolla, California 92037. Agouron does extensive business in the State of New York, including in the County of Westchester. Agouron manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Viracept®.

(e) Pfizer, Pharmacia, Agouron and Sanofi are at times referred to collectively herein as "the Pfizer Defendants."

44. Defendant Schering-Plough Corp. ("Schering") is a highly diversified health



care corporation whose principal business was the development, manufacture and sale of health care products including pharmaceuticals. Schering is a New Jersey corporation, whose headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough does extensive business in the State of New York, including in the County of Westchester. Schering, directly or through its subsidiary Warrick, manufactures and/or sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County including Claritin®.

45. Defendant Takeda Chemical Industries, Ltd. is the largest pharmaceutical company in Japan. Its principal place of business is 1-1 Doshomachi 4-chome, Chuo-ku, Osaka, 540-8645, Japan. Takeda Chemical Industries, Ltd. is the corporate parent of Defendant Takeda Pharmaceuticals North America, Inc.

46. Defendant Takeda Pharmaceuticals North America, Inc. ("Takeda") is principally involved in the discovery, development, manufacture, and sale of pharmaceuticals. Takeda's principal place of business is 475 Half Day Road, Suite 500, Lincolnshire, IL, 60069. Takeda conducts extensive business in the State of New York, including in the County of Westchester. Takeda manufactures and sells prescription drugs with false and inflated AWP's that are paid for by Medicaid in Westchester County, including such medications as Actos®.

47. Defendant TAP Pharmaceutical Products, Inc. ("TAP") is a highly diversified health care company whose principal business was the development, manufacture, marketing and sale of health care products including pharmaceuticals. TAP is a joint venture between defendant Abbott and Takeda Chemical Industries, Ltd., of Osaka, Japan. TAP conducts extensive business in the State of New York, including in the County of Westchester. TAP's principal place of business is 675 North Field Drive, Lake Forest, Illinois 60045. Prior to April,

2000, TAP was known as TAP Holdings, Inc. TAP, together with its subsidiary defendant Tap Pharmaceuticals, Inc., manufactures and/or sells prescription drugs with false and inflated AWP that are paid for by Medicaid in Westchester County, including such medications as Prevacid®.

48. Defendant Warrick Pharmaceuticals Ltd ("Warrick") is a Delaware corporation with its principal place of business at 12125 Moya Boulevard, Reno, Nevada. Warrick is a wholly-owned subsidiary of defendant Schering-Plough and has been since its formation in 1993. Schering-Plough and Warrick manufacture and/or sell prescription drugs with false and inflated AWP that are paid for by Medicaid in Westchester County including such medications as Claritin® and Albuterol®.

49. Defendant Wyeth, formally American Home Products, is a highly diversified health care corporation whose principal business is the development, manufacture and sale of health care products including pharmaceuticals. Wyeth is a Delaware corporation whose principal place of business is Five Giralda Farms, Madison, NJ. Wyeth conducts extensive business in the State of New York, including in the County of Westchester. Wyeth manufactures and/or sells prescription drugs with false and inflated AWP that are paid for by Medicaid in Westchester County, including such medications as Protonix®.

#### **AS YET UNNAMED CO-CONSPIRATORS AND DOE DEFENDANTS**

50. Various other entities, partnerships, sole proprietors, companies, and corporations, presently unknown to Westchester and not named as defendants in this Complaint, participated as co-conspirators in the violations alleged in this Complaint and performed acts and made statements in furtherance thereof. Such unknown parties acted as co-conspirators and aided, abetted, or participated with defendants in the commission of the wrongful acts alleged herein or otherwise caused the damages suffered by Westchester.

51. Except as described herein, plaintiff is, as yet, ignorant of the true names,

capacities, nature and extent of the participation in the course of conduct alleged herein of the persons sued as DOES 1-100 inclusive and, therefore, sues these defendants by such fictitious names. Westchester will amend this Complaint to allege the true names and capacities of the Doe defendants when ascertained.

52. Each of the defendants designated herein as a Doe defendant is legally responsible in some manner for the unlawful acts referred to herein. Plaintiff will seek leave of Court if necessary to amend this Complaint to reflect the true names and capacities of the defendants designated herein as Does when such identities become known.

#### IV. GENERAL ALLEGATIONS

53. The allegations contained herein apply generally to all defendants.

##### A. THE AWP SYSTEM

54. There are approximately 65,000 different drug products in the United States market, including different dosages of the same drug. Prescription drugs are dispensed to patients by or through different types of medical providers, including but not limited to: (a) physicians who administer the drug in an office, (b) retail pharmacies, (c) home infusion pharmacies, and (d) other medical providers, including hospitals (collectively referred to hereinafter as "providers").

55. This case concerns "Covered Drugs", which are those drugs for which, pursuant to N.Y. Soc. Serv. Law § 367-a(9), Westchester's Medicaid pharmacy cost reimbursement rate is pegged to AWP. In New York's statutory scheme, AWP is also known as "Estimated Acquisition Cost" or "EAC."

56. Providers regularly submit claims for reimbursement, seeking payment for the drugs from Medicare, Medicaid, insurers and patients. At all times relevant hereto, defendants knew that the Medicare/Medicaid programs rely on published AWP's to reimburse providers for drugs.

57. AWP's are published for each drug identified by a National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWP's for the tens of thousands of drugs. Medical Economics Company Inc. publishes the Drug Topics RedBook (the "RedBook"). First Data Bank compiles the National Drug Datafile. There is also the American Druggist First Databank Annual Director of Pharmaceuticals and Essential Director of Pharmaceuticals (the "Blue Book") and Medi-Span's Master Drug Database (collectively referred to herein as the "publishers").

58. In periodically announcing the AWP for each drug, the publishers publish the prices that are supplied to them by the defendants for their respective drugs. The forward to the 1999 edition of the RedBook stated that "all pricing information is supplied and verified by the products' manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted." A June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the RedBook, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the AWP generally is not independently determined by the Publishers.<sup>1</sup> Defendants control the prices listed as the AWP's for each drug.

59. A system that bases its reimbursement rates for drugs on the published AWP is thus dependent on the honesty of the drug manufacturers.

60. Extensive and ongoing federal and Congressional investigations, and recent settlements as described herein, have revealed that numerous pharmaceutical manufacturers,

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<sup>1</sup> As if in acknowledgement of the scheme, the forward to the 2002 RedBook now reads:

"All pricing information in RedBook is furnished by manufactures, distributors, and other suppliers. While great care has been taken in compiling the data, we conduct no independent review and therefore cannot guarantee that accuracy of these prices. We continue to regard AWP as one guideline in the pricing equation and to encourage the dissemination of fair, accurate prices by all suppliers." See 2002 Drug Topics® RedBook, Forward (emphasis added).

including certain of the defendants named herein, have engaged in a scheme involving the fraudulent reporting of AWP's for certain prescription pharmaceuticals including but not limited to prescription pharmaceuticals covered by Medicaid.

61. Specifically, defendants' AWP Scheme involves the reporting by each defendant of inflated Average Wholesale Prices. The fraudulent reporting of Average Wholesale Prices has the effect of materially misrepresenting the actual prices paid to defendants by providers, in violation of federal and state law.

62. Defendants know that they can directly control, fabricate and inflate the AWP for their drugs at any time by forwarding to the Publishers a new and higher AWP. Actual transaction price data -- the amounts actually paid by providers for drugs -- is not readily publicly available, and defendants keep this information (on which AWP's should have been calculated) highly confidential and secret. This makes it practically impossible to efficiently calculate Medicaid reimbursements based on anything other than AWP. Defendants' concealment of true best price data is one of the many reasons the facts underlying defendants' fraud are peculiarly within defendants' control, and why any applicable statute of limitations should be tolled.

63. Plaintiff alleges upon information and belief that, in many instances, the AWP reported by defendants bears little or no relationship to the prices actually paid by providers, in direct violation of federal and state law. Rather, the reported AWP's for covered drugs were simply fabricated in furtherance of defendants' scheme to generate the profit spread to providers, to increase defendants' profits at the expense of Westchester and other Medicaid payors, and to control the market for their products.

64. Defendants' pattern of fraudulent conduct in artificially inflating the AWP's for the Covered Drugs ("the AWP Scheme") directly and foreseeably causes and has caused

Westchester to overpay substantially for those drugs, given Westchester's federal and state statutory obligations, of which defendants, at all times relevant, have been aware.

## **B. THE MEDICAID STATUTORY SCHEME**

65. Medicaid was established by Title XIX of the Federal Social Security Act (the "Act"), 42 U.S.C. 1396, *et seq.* (the "Medicaid Program"). The Act mandates the establishment of minimum health and safety standards which must be met by providers and suppliers, such as defendants, participating in the Medicaid Program. While participation in Medicaid is voluntary, once a state agrees to participate, as New York has (most recently at New York Social Services Law § 363 *et seq.*, as amended 1998) the state must comply with all federal statutory requirements.

66. Among other services and supports, the Medicaid Program pays for certain prescription drugs for those who qualify. Under New York law, N.Y. Social Services Law § 367-a, if such a covered drug is a multiple source prescription drug (generic) or a brand name prescription drug for which no upper limit has been set by the Federal Health Care Financing Administration ("HCFA") (now known as the Centers for Medicare & Medicaid Services (CMMS)), then reimbursement under Medicaid is the lower of the providers' usual and customary charge to the general public or the estimated acquisition cost (EAC), of the drug plus a reasonable dispensing fee.

67. The dispensers' usual and customary charge is not available anywhere. As a result and, as a practical matter, reimbursement is based entirely upon EAC.

68. The EAC is calculated by using the AWP for a drug less a percentage discount. New York's Social Services Law § 367-a(9) expressly defines EAC as "the average wholesale price of a prescription drug based upon the package size dispensed from, as reported by the prescription drug pricing service used by the department, less ten percent thereof, and updated monthly by the department." The 2002 New York Medicaid Reimbursement Rate is AWP -10% +



\$3.50/\$4.50 (dispensing fee). As set forth herein and at Exhibit A hereto, and confirmed by governmental studies which estimate the average AWP inflation to be in excess of 20%, even this 10% discounted formula results in an overpayment for covered drugs by Medicaid payors such as Westchester.

69. Thus, Westchester County reimburses providers for Covered Drugs at an amount that is based upon the Covered Drugs' Estimated Acquisition Cost ("EAC") or Average Wholesale Price ("AWP"), as published and reported by the publishers discussed above. As alleged, given that these AWP's are false and inflated, Westchester has been overcharged.

70. In 2001, only one of Westchester's leading Medicaid reimbursed drugs (Albuterol Aer 90 MCG) had a HCFA upper limit established. *See* Exhibit A hereto.<sup>2</sup> For all other drugs where Medicaid reimbursements were made by Westchester, such payments were based on AWP and therefore wrongfully and falsely inflated pursuant to the scheme alleged herein. As Exhibit A makes plain, this means that the vast majority of at least Westchester's top Medicaid reimbursements in 2002 were inflated.

71. As stated, there is another aspect to the Medicaid Statutory Scheme implicated here. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of Health and Human Services. Pursuant to the rebate agreement, the manufacturer promises to report to Medicaid its "best price" and to pay rebates to Medicaid to ensure that the nation's insurance program for the poor receives the same favorable drug prices offered to other large purchasers of drugs. The statute defines the best price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance

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<sup>2</sup> Having an HCFA upper limit may affect damages for Albuterol.

organization, nonprofit entity or governmental entity." The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates" and does not include "prices that are merely nominal in amount."

72. Upon information and belief, each defendant herein entered into such a rebate agreement with the Secretary of Health and Human Services. In that agreement, each agreed to comply with Section § 1396r-8, and hence:

(a) Agreed to report its best price, inclusive of cash discounts, free goods contingent upon any purchase requirements, volume discounts and rebates, in any quarter and to make rebates where necessary;

(b) Agreed that it would determine its best price based upon its average manufacturer's price, calculated as "net Sales divided by numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements)" and that it would include in that calculation cash discounts and all other price reductions "which reduce the actual price paid"; and

(c) Agreed that the best price would not take into account nominal prices, defined as prices that are less than 10 percent of the average manufacturer's price in that quarter, so long as the sale of product at a nominal price was not contingent on any other sale.

73. New York Social Services Law § 367-(a)(7)(d) expressly incorporates the rebate requirements of 42 U.S.C. § 1396r-8 and provides that where a manufacturer has entered into a rebate agreement, as outlined above, Medicaid reimbursements shall be made only pursuant to the terms of that rebate agreement.

74. Non-compliance with the best price requirements carries strict penalties. For example, 42 U.S.C. § 1396r-8(c)(ii) expressly provides that "any manufacturer with an agreement



under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information.”

75. Westchester, like any Medicaid payor, was an intended third party beneficiary of these rebate agreements.

**C. DEFENDANTS' FRAUDULENT CONDUCT RESPECTING  
AWP REPORTING AND FAILURE TO REPORT BEST PRICES**

**1. Artificially Inflating and Fraudulently Reporting AWP**

76. Each Defendant Drug Manufacturer provided directly, or caused to be provided (i.e., through WACs that are converted to AWP) AWP for each of its drugs to the RedBook, the Blue Book, Medi-Span and other pharmaceutical compendia for Covered Drugs.

77. At all times relevant hereto, the defendant drug manufacturers deliberately, routinely and intentionally published or caused to be published AWP for Covered Drugs that did not reflect the actual prices for the drugs. These inflated prices were reported to cause Medicaid and other governmental programs to overpay for the Covered Drugs. The purpose of artificially inflating the providers' profits was to create an illegal kickback to the providers funded by Medicaid and other government insurers. In other words, the scheme was perpetuated so that providers who purchased the drugs at a low cost would bill patients and their insurers at the inflated AWP and earn a substantial profit from the “spread” between the real cost and the various AWP-related reimbursement rates.

78. Defendants knew and understood that Medicaid relied on the RedBook and other compendia to determine the AWP of the covered drugs. Because defendants controlled the published AWP, defendants knew and understood that they could manipulate the providers' profits from Medicaid contributors, such as Westchester.

## 2. Failure to Report Best Prices

79. After execution of the rebate agreement required pursuant to 42 U.S.C. § 1396r-8, each defendant is required to report its average manufacturer's price in each quarter. Yet, consistent with their artificial inflation of AWP to publishers, defendants routinely do not report the actual "best price" but, instead, exclude from best price discounts, free samples and other inducements offered to providers to increase use of a drug being reimbursed by governmental entities at a reimbursement rate pegged to AWP.

80. The AWP scheme succeeds precisely because providers are able to obtain drugs at prices significantly below current Medicaid reimbursements. Most manufacturers sell drug products to physicians and other suppliers at a discount from AWP. Sometimes these discounts are substantial.

81. The widely available prices available from wholesalers and group purchasing organizations ("GPOs") for covered drugs are considerably less than the AWP used to establish the Medicaid reimbursement. For most of the high-expenditure or high volume physician-administered drugs, widely available discounts from AWP range at the low end from 13 percent to 34 percent. Recent ongoing federal investigations and settlements involving certain named defendants reveal much greater discounts sometimes as high as 85%. Providers who have been identified as low-volume billers for certain drugs can also purchase drugs for considerably less than the Medicaid reimbursement.

82. Upon information and belief, each of the defendant pharmaceutical companies has also utilized an array of other inducements to stimulate sales of their drugs. These inducements, including educational grants, volume discounts, and rebates or free goods, were designed to result in a lower net cost to the purchaser while concealing the actual cost price beneath a high invoice price. A product invoiced at \$100 for ten units of a drug might really only cost the

purchaser one-half that amount. If one assumes a subsequent shipment of an additional ten units at no charge, or a "grant," "rebate" or "credit memo" in the amount of \$50, the transaction would truly cost just \$5 per unit net. Through these sort of "off-invoice" means, drug purchasers routinely are provided substantial discounts that induce their patronage while maintaining the fiction of a higher invoice price—the price that corresponded to reported AWP and inflated reimbursement from Medicaid. One example is this from Bayer:

BAYER: "I have been told that our present Kogennate price, \$.66, is the highest price that Quantum is paying for recombinant factor VIII. In order to sell the additional 12mm/u we will need a lower price. I suggest a price of \$.60 to \$.62 to secure this volume."

83. Manufacturers or wholesalers also offer purchasers rebates based on the volume of products purchased not in a single sale but over a period of time. Manufacturers also establish "chargeback" arrangements for purchasers, which result in the AWP overstating what those purchasers pay. Under these arrangements, the purchaser negotiates a price with the manufacturer that is lower than the price the wholesaler charges for the product. The wholesaler provides the product to the purchaser for the lower negotiated price, and the manufacturer then pays the wholesaler the difference between the wholesale price and the negotiated price.

84. The defendants also engage in extensive distribution of free samples through their sales and marketing representatives as a means of lowering price. The free samples are used to offset the total cost associated with the drugs, thereby increasing the "spread". Upon information and belief, and as confirmed by certain recent settlements as described herein, defendants specifically instruct providers to bill the government for the free samples, which defendants know is unlawful. The free samples are not taken into account by the drug companies in calculating the Best Price, which in turns inflates the AWP.

85. Every free sample of a drug for which a provider bills the government

effectively reduces the provider's overall cost for that drug.

86. Thus, while federal and state Medicaid statutes law require the defendants to provide quarterly rebates if they charge more than the lowest or "best price" offered to any commercial customer, the defendants routinely fail to do this. This is because defendants know that, due to practical problems with ascertaining actual cost charges or street prices, Medicaid administrators routinely determine the allowable payment for a prescription drug based upon the AWP reported by the applicable pharmaceutical manufacturer. *See* New York Social Services Law §367-a(9).

87. Recently, two defendants herein, Bayer and GlaxoSmithKline, agreed to pay \$344 million to resolve allegations that they engaged in health care fraud against state programs by failing to report their "best price." The wrongful scheme in which they engaged was known as "lick and stick" wherein they sold re-labeled products to an HMO at deep discounts, and then concealed and avoided their obligations to pay millions of dollars in additional rebates to the Medicaid program.

88. At the time of the offenses, Kaiser Permanente Medical Care Program ("Kaiser") was the nation's largest HMO, providing care and treatment to more than 6 million persons, and often purchased drugs directly from drug manufacturers to save on costs for its members, negotiating aggressively for lower prices. Both Bayer and Glaxo provided discounted prices to Kaiser for their drugs and engaged in private labeling for the HMO, affixing different labels to their drug products. These slightly altered labels allowed Bayer and Glaxo to avoid reporting to the federal government, the new low prices given to Kaiser and avoid paying millions of dollars in additional drug rebates to the Medicaid program. The type of fraud scheme is known as "lick and stick" in reference to the use of a new label on the drug. This is but one example of

the ways in which defendants avoid paying proper rebates.

**D. THE DEFENDANT DRUG MANUFACTURERS' USE OF AWP FRAUD TO INCREASE AND MAINTAIN VOLUME AND MARKET SHARE FOR GENERIC AND MULTI-SOURCE DRUGS**

89. The Defendant Drug Manufacturers' AWP fraud is most exacerbated for generic or multi-source drugs, such as Fluoxetine and Albuterol (two of Westchester's top 2002 Medicaid drugs), for which there are biological or therapeutic equivalents.

90. Multi-source drugs or biologicals are also reimbursed on the basis of AWP. New York's Social Services Law defines AWP for multi-source drugs as equal to the lesser of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicaid.

91. As stated by one industry consultant:

... This situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWP's. ... [T]he system allows a retailer to acquire a drug at a low cost \$2.50 per 100 tablets, for example, while relying on a published AWP (\$20.00 or more) for its own pricing. It is not uncommon that the \$25.00 retail price for a generic drug renders a gross profit well above \$20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines ... It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits.

92. The raising of an individual defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed. As a result, the publication



and reporting of fraudulent AWP by defendants for generic drugs squarely fits generic drugs in which the cure of unlawful AWP inflation within the activity complained of herein. Moreover, while any one generic manufacturer can only effect the median generic reimbursement AWP for a product, defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWP that are far in excess of the actual wholesale prices while simultaneously maintaining or lowering actual wholesale prices.

93. Upon information and belief, generic manufacturers are aware of the AWP reported by their competitors and of the actual sales price of their generic competitors. Generic drug manufacturers manipulate their own AWP in order to gain or maintain a competitive advantage in the market for their generic products. Each defendant generic maker or distributor competes by inflating its AWP and thereby inflating the media AWP. The natural and expected result of the "leap frogging" of increasing AWP is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. A few examples are set forth below:

Defendant	Multisource Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Baxter	Dextrose	\$ 928.51	\$ 2.25	41,167%
Baxter	Sodium Chloride	\$ 928.51	\$ 1.71	54,199%
Boehringer*	Leucovorin Calcium	\$ 184.40	\$ 2.76	6,581%
B. Braun	Sodium Chloride	\$ 11.33	\$ 1.49	660%
BRISTOL-MYERS Group*	Etoposide (Vepesid)	\$ 136.49	\$ 34.30	298%
Dey	Albuterol Sulfate	\$ 30.25	\$ 9.17	230%

Defendant	Multi-source Drug	RedBook AWP	DOJ Determined Actual AWP	Percentage Spread
Immunex*	Leucovorin Calcium	\$ 137.94	\$ 14.58	846%
Pharmacia*	Etoposide	\$ 157.65	\$ 9.47	1,565%
Sicor Group	Tobramycin Sulfate	\$ 342.19	\$ 6.98	4,802%
Watson	Vancomycin HCL	\$ 70.00	\$ 3.84	1,567%

\* Defendants herein.

94. In sum, generic or multi-source drugs are subject to the same fraudulent AWP manipulation as set forth in this Amended Complaint.

#### E. MOTIVATION FOR DEFENDANTS' AWP PRICING SCHEME

95. As stated, the purpose and intent of defendants' fraudulent AWP Scheme is to manipulate and thereby increase the amount of reimbursement received by providers of drugs manufactured and sold by defendants.

96. Specifically, defendants' AWP Scheme contemplates that (a) defendants will intentionally report falsely and fraudulently inflated AWP prices for these drugs to industry publications; and (b) defendants will actually charge providers amounts for these drugs that are substantially less than the AWP that defendants have fraudulently reported.

97. The provider then receives reimbursement from Medicaid, based upon the fraudulently inflated AWP. This circumstance results in a substantial financial incentive to the provider, representing the difference between the inflated AWP-based reimbursement to the provider and the significantly lower direct price charged by defendants to the provider.

98. Defendants refer to the amount received by the provider resulting from the difference between the fraudulently inflated AWP reimbursement and the price actually paid by the

provider as the "spread."

99. Each of the defendants has sought to manipulate the market for drugs at issue by inducing providers to prescribe these drugs, rather than competing drugs, because of the higher "spread" resulting from the falsely and fraudulently inflated AWP.

100. By participating in the AWP Scheme, defendants seek to influence providers to prescribe the drug with the greatest "spread" between the AWP and the actual direct price paid by the provider to the manufacturer. In fact, defendants have greatly increased their profits by manipulating the AWP to create falsely inflated "spreads", which result in financial incentives to providers to prescribe specific drugs subject to the AWP Scheme.

101. The manipulation of AWP at the expense of Medicaid is further revealed when the defendants sell drugs that are not reimbursed by Medicaid. In these circumstances, the drug companies often report accurate AWP's and actually compete with other drug companies on the basis of having a lower AWP than the other company. The company with the lower AWP will urge physicians to consider the cost to the patient when selecting drugs and promote its lower AWP as a selling tool. Thus, when Medicaid is not involved, defendants often ensure that their AWP's are accurate so as to compete for market share based on price.

102. Defendants were aware that providers would purchase and utilize products that have the widest spread between the providers' true costs and the reimbursement paid by third parties. All defendants made representations of their AWP for various drugs, which representations were not accurate. In doing so, defendants hoped that providers would view the inflated AWP as a reason for selecting their drug. Defendants also knew that this selection would be at the expense of governmental payors, like Westchester.

## V. GOVERNMENT INVESTIGATIONS

103. The United States Department of Justice ("DOJ"), the United States General



Accounting Office ("GAO"), the Office of the Inspector General at the United States Department of HHS ("OIG"), and certain Congressional subcommittees have been investigating defendants and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of AWP's and for offering illegal incentives to providers.

104. In connection with the investigation of the United States Congress, Congressman Stark wrote most, if not each, of the defendants herein in a letter dated October 31, 2000:

You should by now be aware of Congressional investigations revealing that Abbott has for many years reported and published inflated and misleading data and has engaged in other deceptive business practices. This letter is a call for your company to immediately cease overcharging taxpayers and jeopardizing public health . . . . The price manipulation scheme is executed through Abbott's inflated representations of average wholesale price (AWP) and direct price ("DP") which are utilized by the Medicare and Medicaid Programs in establishing drug reimbursements to providers. The difference between the inflated representations of AWP and DP versus the true price providers are paying, is regularly referred to in your industry as "the spread." The evidence amassed by Congress clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share of certain drugs. This was achieved by arranging financial benefits or inducements that influenced the decisions of health care providers submitting Medicare and Medicaid claims . . . . Based on the evidence collected, Abbott should make arrangements to compensate taxpayers for the financial injury caused to federally funded programs. Any refusal to accept responsibility will most certainly be indicative of the need for Congress to control drug prices. If we cannot rely upon drug companies to make honest and truthful representations about their prices, then Congress will be left with no alternative but to take decisive action to protect the public.

105. Congressman Stark made the following five "shocking conclusions":

First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a de facto improper kickback for their customers.

Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.

Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.

Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.

Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

106. The Stark materials indicate that defendants employed a number of other financial inducements to stimulate the sales of their drugs at the expense of Medicaid. Such inducements include the practices described herein, i.e., volume discounts, rebates, off-invoice pricing and free goods designed to lower the net cost to the purchaser while concealing the actual cost of the drug from reimbursement officials.

107. Congressman Stark released numerous examples of the manipulation of AWP:

(a) In the 2000 edition of the RedBook, defendant Bristol-Myers reported an AWP of \$1,296.64 for one 20mg/ml, 50ml vial of Vepesid (Etoposide) for injection, while selling the exact same drug in the same quantity to a GPO for \$70. This represents a spread between

Bristol-Myers' falsely inflated AWP and the real price of \$1,226.64. Bristol-Myers is a defendant herein.

(b) Effective January 10, 1995, defendant Glaxo increased the AWP for Zofran by 8.5 percent while simultaneously fully discounting this increase to providers. The net effect of these adjustments was to increase the amount of reimbursements available to providers from Medicaid and others whose reimbursement is based on the AWP. Because the net price paid to Glaxo for the non-hospital sales of the Zofran multi-dose vial is actually lower, it does not appear that the increase in the AWP was designed to increase revenue per unit to Glaxo. Absent any other tenable explanation, this adjustment appears to reflect an intent to induce providers to purchase Zofran based on the opportunity to receive increased reimbursement from Medicaid and other third party payors.

(c) Other examples include Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, a defendant herein, which had a reported AWP of \$241.36 as of April 2000. The real wholesale price was \$33.43. In 1997, when the reported AWP for this drug was \$946.94, it was being offered to physicians for as low as \$152.00.

(d) Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was \$28.38; DOJ found that retailers were buying it for \$1.70.

(e) Amikacin, used to treat an infection that HIV+ people are susceptible to and manufactured by defendant Abbott, had an AWP of \$54.56. The actual best price was \$6.75. Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14.

108. The Department of Health and Human Services, Office of Inspector General

and Department of Justice also are actively investigating the fraudulent pricing practices undergirding this Complaint. Certain of these investigations are discussed in the allegations respecting the individual defendants, *infra*. In sum, however, the investigations confirm unlawful practices herein described.

109. The Office of Inspector General ("OIG") 2001 review estimated that the actual price of brand name prescription drugs was, at the low end, 21.84% below the reported AWP across the board. The OIG estimated that as much as \$1.08 billion nationwide could have been saved for the 200 most frequently reimbursed drugs in Calendar Year 1999, if reimbursement had been based on a greater percentage discount off of AWP, or actual price. Other reports, such as a September 21, 2000 GAO Report had determined that actual prices for top Medicaid/Medicare drugs such as Albuterol (one of Westchester's top Medicaid pharmacy costs) and Ipratropium bromide were 85% and 75% less than their AWP. Applying this range of percentages to Westchester County's Medicaid result in millions of dollars of illegal overcharges since 1995 alone.

110. That same September 21, 2000, GAO report found that:

Widely available discounts for 17 of the physician-billed drugs we examined averaged between 13 percent and 34 percent less than AWP.

For two other physician-billed drugs, Dolasetron mesylate and Leucovorin calcium, average discounts were considerably larger – 65 percent and 86 percent less than AWP

111. The report specifically implicated the conduct of defendants Amgen and Johnson & Johnson with respect to at least one of the drugs, paid for by Westchester as a Medicaid pharmacy cost i.e., epoetin alfa sold as Epogen®.

112. In sum, according to the GAO report, the discounts on physician-billed drugs (based on wholesaler and the GPOs' catalogue prices) were notably lower than Medicaid's payment of ten (10) percent below AWP.

113. The government investigations have confirmed the effectiveness of the AWP scheme. For example, an April 2002 GAO report focusing on sales of a drug in Florida found that Medicaid usage of Vancomycin nearly doubled when Abbott raised the AWP. And when Bayer retained its spread on Whin Rho while other manufacturers did not, its use “skyrocketed.”

114. This is further demonstrated by comments made in publicly available documents by defendants SmithKline Beecham and TAP:

SMITHKLINE: “In the clinic setting however, since Medicare [like Medicaid] reimbursement is based on AWP, product selection is largely based upon the spread between acquisition cost and AWP. . . . Therefore, the spread between the AWP and clinic cost represents a profit to the clinic of \$50.27 for the medication alone. . . . From this analysis, there seems to be no other reason, other than profitability, to explain uptake differentials between the hospital and clinic settings, therefore explaining why physicians are willing to use more expensive drug regimens.”

TAP: “As we have also discussed, Northwest Iowa Urology is very upset about the allowable not going up. I personally met with the doctors to discuss the issue 4/17. The physicians have started using Zoladex but would stop if the allowable issue was taken care of. NWI Urology has 180 patients on Lupron.8”

115. The OIG recently re-admonished pharmaceutical companies to provide an accurate AWP. In its April 2003 report “Compliance Program Guidance for Pharmaceutical Manufacturers,” the OIG reminded that “government sets reimbursement with the expectation that the data **provided are complete and accurate**” (emphasis added). The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

Where appropriate, manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices



should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements.

116. And, the OIG rejected the notion that purposeful AWP manipulation was a lawful practice:

The "spread" is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the "spread," it controls its customer's profit.

Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at "95 percent of average wholesale price." 42 U.S.C. 1395u(o). **Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP.** Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike bona fide discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. **In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.**

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. The

conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute. Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [Emphasis added.]

## VI. ALLEGATIONS PARTICULAR TO WESTCHESTER AND THE INDIVIDUAL DEFENDANTS

117. Westchester's own investigations of pricing data confirm that the Average Wholesale Prices reported by defendants for the Covered Drugs reimbursed by Westchester are fraudulent and inflated. The results of these investigations are set forth below and summarized in Exhibit A hereto.

118. As set forth in detail below for every defendant, Westchester's research establishes that every reported AWP is false and fraudulently inflated, and that Westchester was overcharged for every Covered Drug.

119. Even these overcharge estimates are understatements because they do not include the defendants' failures to report Best Price as required by federal and state rebate statutes. The impact of these failures on the AWP's at issue and Westchester's overcharges as a result will be revealed through discovery of defendants' discounting, promotional and rebate practices. When defendants' failures to report Best Prices are factored in, the spread between reported and true AWP's will be even greater. The facts surrounding defendants' pricing and promotional activities, which implicate the true Best Price for Covered drugs are uniquely within defendants' control at this time.

### A. ABBOTT

120. At all times relevant hereto, Abbott routinely has reported or caused to be reported, inflated average wholesale prices resulting in overcharges to Westchester. Based on

Westchester's investigation, in 2002 alone, Abbott reported inflated AWP's for Kaletra Softgel, Depakote and Flomax as follows:

Drug	Reported Average Wholesale Price	Westchester's Estimated True AWP	Estimated Overcharge	Estimated Overcharge as a percentage of Reported AWP
DEPAKOTE TAB 250MG	\$1.04	\$0.77	\$0.27	26%
DEPAKOTE TAB 500MG	\$1.92	\$1.38	\$0.54	28%
FLOMAX CAP 0.4MG	\$2.01	\$1.45	\$0.56	28%
KALETRA SOFTGEL	\$3.91	\$1.86	\$2.05	52%

121. Upon information and belief, Abbott has engaged in similar inflationary practices in prior years resulting in comparable damage to Westchester for all covered drugs.

122. Even above estimates do not reveal the full impact of Abbott's fraud because they do not include Abbott's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Westchester's overcharges will be revealed through discovery of Abbott's promotional, discounting and pricing practices.

123. When Abbott's failure to report Best Price for these drugs is factored in, the spread between reported AWP and true AWP will be even greater. The facts surrounding Abbott's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Abbott's control at this time and will be revealed through discovery.

124. In connection with its scheme to inflate AWP's, Abbott has been investigated by at least the United States Department of Justice, the United States Congress, Commonwealth of Massachusetts, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for the State of Texas, the Attorney General for the State of California, and the State of California Department of Justice Bureau of Medi-Cal Fraud and Elder Abuse.



125. Recently, Abbott agreed to pay \$622 million in criminal and civil penalties for the activities of its Ross Products Unit in defrauding Medicare and Medicaid in a manner substantively identical to the allegations herein concerning failure to report Best Price. In that proceeding, the U.S. Attorney's Office in the Southern District of Illinois had probed whether Ross Units and its rivals had been using kickbacks to boost sales and defraud government insurers by discounting or giving away products. Providers thereafter would seek government reimbursements at higher prices.

126. Abbott, also and notably, was co-venturer with Japan's Takeda Chemical Industries, Ltd. in TAP Pharmaceuticals, which paid \$875 million in a 2001 settlement of allegations that TAP provided free and unreported samples of Lupron, a prostate cancer drug, to physicians with the understanding that the doctors would bill Medicaid and Medicare for reimbursement at an inflated AWP rate.

127. At all times relevant hereto, Abbott has controlled and set, or caused to be set, the reported AWP for its pharmaceutical products through direct communications with industry compendia.

#### B. AMGEN

128. At all times relevant hereto, Amgen routinely has reported or caused to be reported, inflated AWP, resulting in overcharges to Westchester. Based on Westchester's investigation, in 2002 alone, Amgen reported inflated average wholesale prices for Epogen, Enbrel Kit (Enbrel is manufactured by Immunex and marketed by Amgen and Wyeth) and Neupogen as follows:

Drug	Reported Average Wholesale Price	Westchester's Estimated True AWP	Estimated Overcharge	Estimated Overcharge as a percentage of Reported AWP
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Drug	Reported Average Wholesale Price	Westchester's Estimated True AWP	Estimated Overcharge	Estimated Overcharge as a percentage of Reported AWP
EPOGEN VIAL 40,000U/ML	\$568.00	\$265.71	\$302.29	53%
NEUPOGEN VIAL 300MCG/ML	\$227.60	\$94.04	\$133.56	59%
NEUPOGEN VIAL 480MCG/ML	\$362.60	\$149.63	\$212.97	59%
ENBREL KIT 25MG	\$163.33	\$73.25	\$90.08	55%

129. Upon information and belief, Amgen has engaged in similar inflationary practices in prior years resulting in comparable damage to Westchester for all covered drugs.

130. Amgen has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price.

131. A 1993 OIG Report detailed how Amgen gave substantial year-end rebates to its customers based on their purchases of Epogen. The report noted that Medicare and Medicare beneficiaries did not receive the benefit of any rebates; all monies remained with the provider. There was no way to provide for any rebates on Medicare claim forms, and Amgen's rebates were not provided until year-end:

[T]he effect of the rebates is that it reduces the actual cost of EPO to a dialysis facility, thus increasing their gross profit. Presently, the rebates represent price reductions which benefit the facilities exclusively.

132. By utilizing hidden inducements, Amgen provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

133. Even the estimates and inflated AWP's set forth above are understated

because Westchester's estimates do not take into account Amgen's failures to include Best Price as required by federal and state statute. The full impact of these failures on Westchester's overcharges will be revealed through discovery of Amgen's promotional, discounting and pricing practices.

134. When Amgen's failure to report Best Price for the drugs paid for by Westchester is factored in the spread between reported AWP and true AWP will be even greater. The facts surrounding Amgen's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within Amgen's control at this time and will be revealed through discovery.

135. At all times relevant hereto, Amgen has controlled and set, or caused to be set, the reported AWP's for its pharmaceutical products through direct communications with industry compendia.

### C. ASTRAZENECA

136. At all times relevant hereto, AstraZeneca routinely has reported or caused to be reported, inflated AWP's, resulting in overcharges to Westchester. In 2002 alone, based on Westchester's investigation, AstraZeneca reported inflated average wholesale prices for Prilosec, Nexium, Pulmicort, Casodex, and Seroquel as follows:

Drug	Reported Average Wholesale Price	Westchester's Estimated True AWP	Estimated Overcharge	Estimated Overcharge as a percentage of Reported AWP
SEROQUEL TAB 300MG	\$7.22	\$3.34	\$3.88	54%
CASODEX TAB 50MG	\$14.03	\$9.69	\$4.34	31%
NEXIUM CAP 40MG	\$4.14	\$3.03	\$1.11	27%
PRILOSEC CAP 20MG	\$4.49	\$3.05	\$1.44	32%
PULMICORT 20 MG Inhaler	\$146.39	\$98.94	\$47.45	32%



Drug	Reported Average Wholesale Price	Westchester's Estimated True AWP	Estimated Overcharge	Estimated Overcharge as a percentage of Reported AWP
SEROQUEL TAB 100MG	\$2.91	\$2.17	\$0.74	26%
SEROQUEL TAB 200MG	\$5.48	\$3.96	\$1.52	28%
SEROQUEL TAB 25MG	\$1.60	\$1.20	\$0.40	25%

137. Upon information and belief, AstraZeneca has engaged in similar inflationary practices in prior years resulting in comparable damage to Westchester for all covered drugs manufactured by AstraZeneca.

138. Even these investigations do not reveal the full impact of AstraZeneca's fraud because Westchester's estimates do not include AstraZeneca's failures to report Best Price as required by federal and state rebate statutes. The full impact of these failures on Westchester's overcharges will be revealed through discovery of AstraZeneca's promotional and pricing practices.

139. When AstraZeneca's failure to report Best Price for these drugs is factored in the spread between reported AWP and true AWP will be even greater. The facts surrounding AstraZeneca's discounting and rebate activities, which affect the Best Prices for its drugs, are uniquely within AstraZeneca's control at this time and will be revealed through discovery.

140. In connection with the improper AWP scheme discussed herein, AstraZeneca has been investigated by at least the United States Department of Justice, the Office of the Inspector General of the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration. In January 2002, a federal grand jury in Wilmington, Delaware returned an indictment accusing a New Jersey doctor of conspiring with AstraZeneca to resell free samples of Zoladex® that an AstraZeneca sales representatives had given the doctor. The indictment alleged

that AstraZeneca (i) sold Zoladex® to the New Jersey doctor and others at prices substantially below the AWP reported by AstraZeneca, and (ii) provided the New Jersey doctor with materials showing how much more profit he could make by using Zoladex® instead of its competitor, Lupron®.

141. In June, 2003, AstraZeneca pled guilty and paid \$354.9 million to settle the Zoladex charges. As the U.S. Food and Drug Administration said in its statement regarding the settlement, "AstraZeneca provided thousands of free samples of Zoladex to physicians knowing that they would charge their patients and insurance programs for the samples."

142. Upon information and belief, the Zoladex example is merely one of the ways in which AstraZeneca wrongfully and falsely has inflated its reported AWPs. This unlawful activity, has resulted in excessive overpayments by Westchester.

143. On May 29, 2003, AstraZeneca entered into a Corporate Integrity Agreement ("CIA") with the OIG of the United States Department of Health and Human Services "to promote compliance" "with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. 1320a-7b(f))" ("Federal Health Care Program Requirements"). Contemporaneously AstraZeneca entered into a Settlement Agreement with the United States and various states.

144. The CIA covers any individuals who sell or market government reimbursed products on behalf of AstraZeneca; calculate or report prices; and/or include negotiate, implement or report information related to government contracts relating to federal health care programs, including Medicare and the Medicaid Drug Rebate program (codified at 42 U.S.C. 1396r-8 et seq.) The CIA also covers any AstraZeneca employee or agent responsible for "(1) sales and marketing activities for Government Reimbursed Products; (2) the calculation and reporting of prices for

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff the County of Westchester prays for judgment against all defendants as follows:

389. Awarding plaintiff actual, statutory, treble and all other available damages, with interest for defendants' violation of 18 U.S.C. § 1962(c);

390. Adjudging and decreeing that defendants have engaged in the intentional fraudulent conduct alleged herein in violation of N.Y. Soc. Serv. Law §§ 367(a)(7)(d), 366-b and 42 U.S.C. § 1396r-8 and 18 N.Y.C.R.R. 515.2(b)(4) and (5);

391. Awarding Westchester actual, statutory, treble and all other available money damages, with interest, for defendants' violation of N.Y. Gen. Bus. Law § 349 in an amount to be determined at trial;

392. Awarding Westchester actual, statutory, treble and all other available money damages, with interest, for defendants' violation of N.Y. Soc. Serv. Law § 145-b in an amount to be determined at trial;

393. Awarding Westchester actual and compensatory damages in an amount to be determined at trial, with interest, for defendants' breach of contract;

394. Awarding Westchester actual and punitive damages in an amount to be determined at trial, with interest, for defendants' intentional fraud;

395. Ordering defendants each to prepare an accounting to determine the amounts defendants have illegally profited at Westchester's expense, and disgorgement to Westchester of such monies, with interest;

396. Imposing a constructive trust and ordering defendants to pay restitution to Westchester in the amount Westchester has been overcharged for Covered Drugs, with interest;

397. Awarding plaintiff the costs of the suit, including costs, reasonable

# EXHIBIT D



Region IX  
Office of Audit Services  
90 - 7<sup>th</sup> Street, Suite 3-650  
San Francisco, CA 94103

AMGEN-BST0004042261

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Page 2 - Mr. Fred Manak

**Direct Reply to HHS Action Official:**

Jeff Flick  
Regional Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Region IX  
90 – 7<sup>th</sup> Street, Suite 5-300 (5W)  
San Francisco, California 94103-3501

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## *Office of Inspector General*

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## OAS FINDINGS AND OPINIONS

The designation of financial or management practices as questionable or a recommendation for the disallowance of costs incurred or claimed, as well as other conclusions and recommendations in this report, represent the findings and opinions of the HHS/OIG/OAS. Authorized officials of the HHS divisions will make final determination on these matters.







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## INTRODUCTION

### BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) covers a limited number of outpatient prescription drugs and biologicals through its Medicare Part B program. Covered drugs include injectable drugs administered by a physician; certain self-administered drugs, such as oral anticancer drugs and immunosuppressive drugs; drugs used in conjunction with durable medical equipment; and some vaccines.

#### Average Sales Price Calculation

Section 1847A of the Social Security Act (the Act), as added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, established a new methodology for Medicare Part B reimbursement of most covered drugs. In January 2005, Medicare began basing payment for most Part B drugs on the average sales price (ASP). Section 1847A(c) of the Act defines the ASP as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug that the manufacturer sold in the same quarter. The ASP calculation excludes nominal sales and sales excluded from the determination of "best price" in the Medicaid drug rebate program. The ASP is net of price concessions.

CMS recognized that some price concessions are not known in time to be included in the ASP calculation. Federal regulations (42 CFR § 414.804(a)(3)) require that to the extent that price concession data are available on a lagged basis, manufacturers must use a specified 12-month rolling average methodology to estimate these concessions for the quarter. The methodology produces a ratio of 12 months of price concessions to 12 months of sales that is multiplied against quarterly sales to generate quarterly lagged price concessions.

Pursuant to section 1927(b)(3)(A)(iii) of the Act, incorporated by reference in section 1847A(f), manufacturers report ASPs by national drug codes (NDC). NDCs, as used for ASPs, are 11-digit identifiers that indicate the manufacturer, product dosage form, and package size of a drug. Manufacturers must provide CMS with the ASP and volume of sales for each NDC on a quarterly basis within 30 days after the close of the quarter (section 1927(b)(3)(A) of the Act).

Although manufacturers submit ASP data by NDCs, CMS does not use NDCs to reimburse Medicare providers for drugs. Instead, CMS uses procedure codes (known as "J" or "Q" codes). More than one NDC may meet the definition of a particular procedure code. Generally, for each procedure code, CMS calculates a quarterly ASP based on 106 percent of the weighted average of ASP data reported by manufacturers (section 1847A(b) of the Act).

In addition to the methodology established in the Act and regulations, CMS has provided additional guidance in the preambles to the regulations. For example, CMS's "Interim Final Rule" (69 Federal Register 17935 (April 6, 2004)) provides instructions to manufacturers responsible for calculating ASPs. The preamble includes instructions for allocating price concessions to associated NDCs when the manufacturer is not able to associate the concessions with a specific NDC, as well as requirements for the manufacturer's certification of the ASP

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submission. Starting in September 2004, CMS issued additional guidance for ASP submissions in the form of more than 30 Frequently Asked Questions and Answers (Q&A) that can be found on CMS's Web site.<sup>1</sup> Appendix A provides a detailed description of the ASP calculation.

**Amgen USA, Inc.**

Amgen USA, Inc. (Amgen) develops, manufactures, and markets products in the areas of inflammation, nephrology, and supportive cancer care. Amgen submitted an ASP on July 26, 2005, for Aranesp, a Medicare Part B drug used to treat anemia associated with chronic renal failure and chemotherapy.

According to Amgen, it developed standard operating procedures and calculation templates to calculate ASPs for all of its products. The methodology is summarized in Appendix B.

**OBJECTIVE, SCOPE, AND METHODOLOGY**

**Objective**

Our objective was to determine whether Amgen's ASP calculation methodology for Aranesp complied with Federal requirements and guidance.

**Scope**

Our audit focused on Amgen's second-quarter 2005 ASP of \$561.88 for Aranesp NDC 55513004401, a brand-name drug. Amgen submitted the ASP to CMS on July 26, 2005. We did not verify Amgen's assertion that it used the same methodology for all of its products. We reviewed only those internal controls necessary to achieve our objective.

We conducted our fieldwork at Amgen's offices in Thousand Oaks, California.

**Methodology**

To accomplish our objective, we:

- reviewed applicable Federal laws and regulations and CMS guidance;
- reviewed Amgen's policies and procedures for its ASP filing;
- interviewed Amgen representatives to obtain an understanding of the methodology and assumptions used to calculate the ASP;
- interviewed CMS officials about the Federal requirements and guidance governing ASP submissions and any concerns with Amgen's ASP;

<sup>1</sup>CMS, "Average Sales Price." Available online at <http://www.cms.hhs.gov/McrPartBDrugAvgSalesPrice/>. Accessed June 28, 2007.

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- evaluated the written methodologies and assumptions that Amgen submitted with its ASP filing;
- selected Aranesp NDC 55513004401 for detailed review of supporting documentation of the ASP calculations;
- verified Amgen's sales and price concessions reported in its Aranesp ASP calculation against accounting records and source documentation, including spreadsheets; marketing materials; and contracts with wholesalers, group purchasing organizations (GPO), and hospitals, among others;
- verified the mathematical accuracy of the ASP calculations; and
- recalculated the quantifiable ASP errors based on Federal requirements and guidance.

We performed our review in accordance with generally accepted government auditing standards.

**FINDINGS AND RECOMMENDATIONS**

Overall, Amgen's ASP calculation methodology for Aranesp complied with Federal requirements and guidance. However, \$1.44 of the \$561.88 Aranesp ASP did not comply with Federal requirements or contained minor calculation errors.

**LAGGED CALCULATION NOT IN COMPLIANCE**

Federal regulations (42 CFR § 414.804(a)(2)) require manufacturers to deduct certain price concessions when calculating their ASPs. Federal regulations (42 CFR § 414.804(a)(3)) also require manufacturers to estimate the price concession amount using a 12-month rolling average methodology to the extent price concessions are available on a lagged basis. The methodology requires manufacturers to calculate a percentage equal to price concessions for the most recent 12-month period available divided by sales for the same 12-month period.

In totaling price concessions and sales for the 12-month period July 1, 2004, to June 30, 2005, Amgen did not comply with Federal requirements, which resulted in a net overstatement to the ASP of \$1.99.

Amgen did not include in the lagged calculation of price concessions \$4,860,940 of wholesaler purchase credits and wholesaler distribution agreement service fees. Instead, Amgen reduced sales by this amount. As a result, Amgen overstated the reported ASP by \$2.74.

In addition, Amgen improperly included \$5,595,722 of discounts known at the time of sale in the calculation of lagged price concessions. Discounts known at the time of sale should not be included in the 12-month rolling average methodology because the methodology is specifically intended to estimate price concessions that are available only on a lagged basis. Because Amgen included these discounts, Amgen understated the reported ASP by \$0.75.

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## MINOR CALCULATION ERRORS

CMS requires manufacturers to certify that the quarterly ASPs were calculated accurately and that all information is true, complete, and current (69 Federal Register 17941 (April 6, 2004)). The following minor calculation errors resulted in a net understatement to the ASP of \$0.55:

- Amgen improperly calculated State Pharmaceutical Assistance Program (SPAP) sales. In addition, Amgen excluded rebates that did not qualify as SPAP rebates and included discounts that related to SPAP sales. As a result, the reported ASP was overstated by \$0.59.
- Amgen understated the amount of excludable sales and chargebacks to non-U.S. entities, causing the reported ASP to be overstated by \$0.16.
- Amgen mistakenly included wholesaler distribution agreement service fees related to multiple products as rebates for our NDC, causing the reported ASP to be understated by \$1.30.

## RECOMMENDATIONS

We recommend that Amgen:

- ensure that all components of its ASPs comply with established criteria and guidance and
- consult with CMS to determine whether the findings in this report warrant refiling of previously submitted ASPs.

## AMGEN'S COMMENTS

In written comments on our draft report, Amgen stated that it does not intend to contest the findings and will adopt our recommendations. Amgen stated that it treated wholesaler price concessions as nonlagged but does not concur that this treatment did not comply with Federal requirements. However, Amgen stated that it is willing to revise its treatment of these transactions. Amgen's comments are included in their entirety as Appendix C.

## OFFICE OF INSPECTOR GENERAL'S RESPONSE

Regarding the treatment of wholesaler price concessions, Amgen included these concessions in the lagged calculation as a reduction to 12-month sales (the denominator) rather than as an addition to 12-month price concessions (the numerator). Amgen should include wholesaler price concessions in 12-month price concessions and not deduct them from 12-month sales.

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#### **OTHER MATTER: ADMINISTRATIVE FEES EXCLUDED**

The methodology that Amgen used included an assumption related to the treatment of administrative fees that we intend to bring to CMS's attention so that CMS may consider issuing additional guidance. In the December 2006 "Final Rule"<sup>2</sup> addressing a variety of Medicare Part B payment issues, CMS provided additional guidance on ASP calculations and administrative fees. However, except to the extent that administrative fees meet the definition of service fees, CMS did not provide specific guidance on the treatment of fees paid by manufacturers to GPOs in the ASP calculation. Additional guidance is needed.

CMS guidance (Q&A 3318) states that manufacturers should include administrative fees paid to an entity whose sales are included in the ASP calculation and ultimately affect the price realized by the manufacturer.

Amgen excluded approximately \$35.3 million of administrative fees paid to GPOs related to Aranesp from its 12-month lagged calculation. Amgen stated that it excluded these fees because GPOs do not directly purchase drugs.

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<sup>2</sup>Revisions to Payment Policies . . . Changes to Payment Under Part B for CY 2007," 71 Federal Register 69623 (December 1, 2006) (in part amending 42 CFR §§ 414.802 and 414.804).

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## APPENDIXES

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## APPENDIX A

## AVERAGE SALES PRICE METHODOLOGY

Average Sales Price (ASP) Calculation Steps	Criteria Citations		Explanatory Comments/Additional Guidance
	Social Security Act	42 CFR 414.804	
1 Total Sales in the United States for the Quarter	1847A(c)(1)(A)	(a)(1)	Question and Answer (Q&A) 3311 states exclude sales in the commonwealth and trust territories or protectorates.
2 Less: Sales Excluded from Medicaid Best Price	1847A(c)(2)(A)	(a)(4)	
a. Prices to Indian Health Services			
b. Prices to Veterans Affairs			
c. Prices to State homes receiving funds under Title 38			
d. Prices to Department of Defense			
e. Prices to Public Health Service (PHS)	1927(c)(1)(C)(i)	(a)(4)	
f. Prices to covered entities described in section 1927(a)(5)(B)			
g. Prices under the Federal Supply Schedule			
h. Prices under a State pharmaceutical assistance program			
i. Prices under any depot and single award contract			
j. Prices negotiated by a Medicare Part D prescription drug plan			
k. Sales at nominal price	1847A(c)(2)(B); 1927(c)(1)(C)(ii)(iii)	(a)(4)	
3 Less: Price Concessions			Per regulation, use 12-month calculation for lagged data. 69 Federal Register 17935 (April 6, 2004) states for data not available at national drug code (NDC) level, allocate based on sales dollars. If conditions met, Q&A 3318 states include administrative fees; Q&A 4136 states exclude certain service fees.
a. Volume Discounts	1847A(c)(3); (c)(5)(A)	(a)(2); (a)(3)	
b. Prompt Pay Discounts			
c. Cash Discounts			
d. Free Goods			
e. Chargebacks			
f. Rebates			
4 Net ASP Sales (1-2-3)			Q&A 3313 states do not include returns.
5 Net ASP Units	1847A(c)(1)(B)	(a)(4)	Q&A 3313 states do not include returns.
6 ASP for the NDC for the Quarter (4/5)	1847A(c)(1)	(a)(1)	Q&A 3323 states submit assumptions to the Centers for Medicare & Medicaid Services.

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## APPENDIX B

**AMGEN USA, INC.**  
**AVERAGE SALES PRICE FOR QUARTER ENDED 6/30/2005**  
**ARANESP – NATIONAL DRUG CODE: 55513004401**

Quarterly Gross Ex-factory Sales <sup>1</sup>	\$330,000,334
Direct Sales Adjustment <sup>2</sup>	2,207,081
U.S. Territories (Puerto Rico, Virgin Islands)	(257,393)
Federal Government <sup>3</sup>	(33,336,424)
State Pharmaceutical Assistance Programs (SPAP) <sup>4</sup>	(141,052)
<b>Quarterly Net Ex-factory Sales</b>	<b>\$298,472,546</b>
<b>Quarterly ASP Sales (Sales Less Estimated Discounts)<sup>5</sup></b>	<b>\$192,430,288</b>
[Qtr Net Ex-factory Sales – (Qtr Net Ex-factory Sales × 35.53% <sup>6</sup> (rounded))]	
Gross Ex-factory Units	381,360
U.S. Territories (Puerto Rico, Virgin Islands)	(456)
Federal Government	(38,269)
State Pharmaceutical Assistance Programs	(162)
Free Goods Units	-
<b>Net Ex-factory Units</b>	<b>342,473</b>
<b>ASP per NDC (Pack)</b>	<b>\$561.88</b>

<sup>1</sup>Ex-factory sales are direct sales from Amgen USA, Inc., to wholesalers and direct ship customers. Based on CMS guidance, Amgen did not reduce sales and units by the value of returns. As an internal control procedure, Amgen reconciled sales from its sales journal to its general ledger.

<sup>2</sup>The direct sales adjustment represents the discount given to direct ship customers at the time of sale. The adjustment is added to gross ex-factory sales so that direct sales are shown at wholesaler acquisition cost.

<sup>3</sup>This category includes sales to the Department of Defense, the Department of Veterans Affairs, the Coast Guard, federally funded Public Health Service (PHS) hospitals, and PHS outpatient and disproportionate share inpatient facilities. The amount of quarterly Federal Government sales and units is an estimate based on the ratio of 12-month Federal Government sales to 12-month gross ex-factory sales. Amgen used chargeback data based on the invoice date.

<sup>4</sup>This category includes sales to AIDS drug assistance programs and waiver programs. The amount of quarterly SPAP sales and units is an estimate based on the ratio of 12-month SPAP sales to 12-month gross ex-factory sales.

<sup>5</sup>All price concessions associated with non-exempt purchasers, including prompt payment discounts, chargebacks, and rebates (including pharmacy benefits manager rebates) are calculated on a lagged basis using a 12-month methodology. All concessions are based on date paid. The 12-month period was inclusive of the current quarter.

<sup>6</sup>This percentage is the result of the 12-month rolling average methodology and is determined by dividing 12-month price concessions by 12-month net ex-factory sales.

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**APPENDIX C**

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**AMGEN**

May 29, 2007

Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799  
805.147.1000  
www.Amgen.com

Ms. Lori A. Ahlstrand  
U.S. Department of Health and Human Services  
Office of Inspector General  
Office of Audit Services  
Regional Inspector General for Audit Services  
San Francisco Federal Building  
90 - 7th Street  
Suite 3-650  
San Francisco, CA 94103

Re: Report Number: A-09-06-00053

Dear Ms. Ahlstrand:

We are in receipt of the draft report entitled "Audit of Amgen USA, Inc.'s Second Quarter 2005 Average Sales Price Calculation for Aranesp" dated April 2007, in addition to your cover letter dated April 16, 2007 forwarding that draft report. Your letter requested that we provide written comments in response to the draft report's findings and recommendations. Your letter specifically requested that such comments include:

- a separate statement of concurrence or nonconcurrence with the facts, conclusions, and recommendations as presented in each of the findings and,
- in the event of nonconcurrence with the facts, conclusions, or recommendations, specific reasons for the nonconcurrence, preferably citing details with which you disagree.

This letter provides Amgen's written comments regarding each of the draft report's findings and recommendations. Your letter had requested these comments by May 15, but by e-mail dated May 4, 2007, [REDACTED] of your office provided Amgen with an extension until May 30.

Overall Findings

The draft report states that, overall, Amgen's ASP calculation methodology for Aranesp® complied with Federal requirements and guidance. As discussed below, the report identified minor calculation errors and methodology issues, affecting \$1.44, or 0.26%, of the \$561.88 audited ASP.

Amgen appreciates the thoroughness of the OIG audit and the cooperative interactions between our price reporting team and the OIG audit team. Amgen does not intend to contest the findings in the draft report and will adopt its recommendations.

**Office of Inspector General Note:** The name of the auditor was redacted.

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## APPENDIX C

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Lagged Calculation Not In Compliance

Amgen has agreements with wholesalers under which it provides wholesalers certain purchase credits and distribution agreement fees, which Amgen includes in the ASP methodology as price concessions. Amgen's ASP calculation to date has been to include these price concessions in the ASP calculation on a non-lagged basis, consistent with Amgen's financial accounting treatment of those transactions. The audit report finds that Amgen's treatment of these transactions as non-lagged "did not comply with Federal requirements," and resulted in an overstatement of ASP by \$2.74.

We do not concur that the treatment of these wholesaler price concessions as non-lagged did not comply with Federal requirements, as the Federal requirements do not specifically state how to include and deduct wholesaler purchase credits and wholesaler distribution agreement fees in the ASP calculation. In the absence of such specific direction, Amgen made a reasonable assumption to treat these transactions consistently with their financial accounting treatment, which was to treat them on a non-lagged basis. However, Amgen is willing to adopt the OIG's recommendation to treat the wholesaler transactions as lagged, and Amgen will revise its treatment of these transactions to comply with the OIG's interpretation.

Amgen also provides discounts at the time of sale to certain purchasers, and has treated those discounts as lagged in its ASP calculation methodology. The audit finds that Amgen's treatment of these discounts as lagged rather than non-lagged was not in compliance with Federal requirements, resulting in an understatement of ASP by \$0.75. Amgen concurs with this finding, but notes that the impact of Amgen's prior approach was to understate, rather than overstate, the reported ASP.

In both cases, Amgen will implement the OIG's recommendations: to treat the wholesaler purchase credits and distribution agreement fees as lagged and discounts provided at the time of sale as non-lagged. Amgen will communicate with CMS about the treatment of these transactions in Amgen's ASP methodology.

Minor Calculation Errors

We concur with the OIG's facts, conclusions and observations with respect to the three minor calculation errors noted in the second quarter 2005 ASP calculation, including:

- Improperly calculating the State Pharmacy Assistance Program (SPAP) sales and related SPAP rebates,
- Understating the amount of excludable sales and chargebacks to non-U.S. entities, and
- Mistakenly including wholesaler distribution agreement services fees related to multiple products to the Aranesp product and related National Drug Code (NDC) selected for testing.

Amgen has determined that the three errors mentioned above were isolated incidents resulting from errors in manual data inputs, affecting only the second quarter 2005 ASP calculation. Previous and subsequent ASP quarterly calculations were not affected by these errors. Amgen has implemented an automated calculation system in the intervening period, which should significantly reduce, if not eliminate, the possibility of such errors occurring in the future.

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**APPENDIX C**

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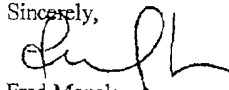
Other Matter- Administrative Fees Excluded

The audit also states the OIG's position that additional guidance is needed from CMS regarding the treatment of administrative fees paid to Group Purchasing Organizations ("GPOs"), and notes that Amgen's methodology does not treat those fees as price concessions in the ASP methodology. We believe Amgen's exclusion of administrative fees paid to GPOs is appropriate and in accordance with established CMS criteria and guidance. As previously disclosed to CMS, all service fees paid to non-exempt purchasers were included in the 12-month methodology, except for those fees that represent a fair market value payment for a bona fide service and that are not passed on in whole or in part to a client or customer of the purchaser. Administrative fees paid to Group Purchasing Organizations ("GPOs") on purchases by their non-owned members were not included in the calculation of ASP, because the GPO itself is not a purchaser, although we understand that some GPOs may unilaterally pass on some of these administrative fees to their members, and some GPOs may be affiliated with one or more wholesalers of Amgen products.

We request that the Office of Inspector General (OIG) maintain the confidentiality of the enclosed submission and of all Amgen related information therein to the maximum extent permitted by law. Specifically, we request that, in accordance with the Freedom of Information Act (FOIA), OIG's FOIA regulations, and Executive Order 12600, the OIG protect from public disclosure all of the information provided in this letter and any related or referenced materials. We believe that all of this information is confidential commercial or financial information not subject to disclosure under FOIA and hereby designate such information as exempt from disclosure under Exemption 4 of FOIA. When any of this designated information is requested under the FOIA or otherwise, we request that the OIG notify us of the request and afford us the opportunity to submit objections to disclosure.

We thank you for this opportunity to comment on the draft report. Please feel free to contact me if you would like to discuss any of these matters in further detail.

Sincerely,



Fred Manak  
Executive Director  
Trade, Pricing and Contract Management  
Amgen USA Inc.

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# EXHIBIT E

Douglas F. Johnson, Esq.  
EARP COHN P.C.  
20 Brace Road, 4th Floor  
Cherry Hill, NJ 08034  
(856) 354-7700

Attorneys for Plaintiff  
Ortho Biotech Products L.P.

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY

-----	X	
ORTHO BIOTECH PRODUCTS, L.P.,	:	
	:	
Plaintiff,	:	
	:	Civil Action No. _____
- v. -	:	
	:	COMPLAINT AND
AMGEN INC.,	:	JURY DEMAND
	:	
Defendant.	:	
	:	
-----	X	

Plaintiff Ortho Biotech Products, L.P. ("Ortho"), a New Jersey limited partnership with its principal place of business located at 430 Route 22 East, Bridgewater, NJ 08807, upon knowledge with respect to its own acts and upon information and belief with respect to all other matters, alleges by way of Complaint against Defendant Amgen Inc. ("Amgen"), a Delaware corporation with its principal place of business located at One Amgen Center Drive, Thousand Oaks, CA 91320, as follows:

**SUMMARY OF CLAIMS**

1. This antitrust action, brought under Sections 1 and 2 of the Sherman Act, involves an anti-competitive tying arrangement and pricing scheme

implemented by defendant Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen's Red Blood Cell Growth Factor ("RBCGF") drug to its dominant White Blood Cell Growth Factor ("WBCGF") drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen's scheme is to monopolize the market for sales of RBCGF drugs to oncology clinics. The result will be less competition, less physician and patient choice and an increased expense to the public health system.

2. Ortho sells Procrit®. Amgen sells Aranesp®. Both are RBCGF drugs that compete head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products are projected to exceed \$2.8 billion in 2005.

3. Amgen also sells Neulasta® and Neupogen®, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

4. Aranesp now accounts for roughly 66% of RBCGF drug sales to oncology clinics. Aranesp's share has increased by 46% over the past 18 months as the result of Amgen's illegal pricing practices that penalize oncology clinics on purchases of its monopoly WBCGF drugs, when those clinics do not agree to purchase significant volumes of its Aranesp, instead of Procrit.

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive. Amgen has now imposed even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase up to 75% of their RBCGF drugs from Amgen. In fact, if a clinic wishes to continue to receive the

same level of rebates it had been receiving under the pre-October 1, 2005 contract, the clinic must increase its Aranesp share up to 90%.

6. Amgen's pricing scheme has reached the point where, for a substantial percentage of its patients, an oncology clinic is put in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. The clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when they purchase virtually all of their RBCGF drug requirements from Amgen.

7. Defendant's conduct constitutes a tying arrangement in violation of Section 1 of the Sherman Act under either a *per se* or Rule of Reason analysis. As the result of Amgen's monopoly power in the sale of WBCGF drugs to oncology clinics, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. Moreover, WBCGF and RBCGF drugs are distinct and separate products and a not insubstantial amount of commerce is involved.

8. Amgen's actions also violate Section 2 of the Sherman Act. The purpose of Amgen's anticompetitive pricing scheme is to monopolize the oncology clinic market for RBCGF drugs in the United States in which Procrit is Amgen's only competitor. There is a dangerous probability that, by engaging in this exclusionary conduct, Amgen will succeed in its monopolistic plans.

9. The anticompetitive conduct at issue here will irreparably harm Ortho and is not in the public interest. If Amgen is not blocked from pursuing this new

pricing scheme, Procrit's ability to compete in the oncology clinic market for RBCGF drugs largely will cease. Since Procrit was introduced in 1991, it has been used to treat millions of patients who suffer from chemotherapy-induced anemia ("chemo-induced anemia"). Procrit was the first RBCGF drug on the market and it improved the lives of millions of patients. Ortho is viewed by thought leaders in the oncology market as one of the pioneers in addressing the needs of cancer patients undergoing chemotherapy. As a result, Ortho has longstanding relationships with oncology clinics and has built-up enormous goodwill in the Procrit brand.

10. Moreover, denying clinics and ultimately patients' access to Procrit is not in the public interest and will harm consumers. Physicians should not face economic coercion. Forcing physicians who treat cancer patients to abandon Procrit as the only economically viable way to gain access to another badly needed drug for their patients, is not, by any measure, in the public interest.

11. For these reasons and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Ortho seeks a preliminary and permanent injunction as well as treble damages.

#### **JURISDICTION AND VENUE**

12. This complaint is filed under Section 16 of the Clayton Act, 15 U.S.C. § 26, to prevent and restrain violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1 and 2, and for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15. This Court has jurisdiction over the federal antitrust law claims alleged herein under 28 U.S.C. §§ 1331, 1337, 2201 and 2202.

13. Defendant transacts business and is found in this district.

Substantial interstate trade and commerce involved and affected by the alleged violations of antitrust law occurs within this district. The acts complained of have had, and will have, substantial anticompetitive effects in this district. Venue is proper in this district under 28 U.S.C. § 1391 and 15 U.S.C. §§ 15, 22 and 26, particularly as plaintiff Ortho resides here.

### **THE PARTIES**

14. Plaintiff Ortho is a limited partnership organized and existing under the laws of New Jersey with its principal place of business located in Bridgewater, New Jersey. Ortho is one of the Johnson & Johnson family of companies. Johnson & Johnson is a corporation with its principal place of business in New Brunswick, New Jersey. Ortho sells Procrit, the drug that is the target of Amgen's monopolistic schemes.

15. Defendant Amgen is a corporation organized and existing under the laws of Delaware with its principal place of business in Thousand Oaks, California. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

### **FACTUAL ALLEGATIONS**

#### **A. Ortho and Amgen are the Only Competitors in the Sale of RBCGF Drugs to Oncology Clinics.**

##### **Procrit**

16. Severe anemia is most commonly seen in patients (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red

blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

17. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

18. Ortho sells Procrit®, a branded version of epoetin alfa. By Product License Agreement (“PLA”) executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen’s patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease (“ESRD”). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen®.

19. At the time of the PLA, the use of epoetin alfa to combat dialysis-induced anemia offered the greatest possibility for commercial success. However, there was no firm basis for predicting the viability of using epoetin alfa to treat anemia resulting from other disease states. Through costly research and clinical trials, Ortho demonstrated the efficacy of epoetin alfa to treat and reduce the need for transfusions in patients undergoing treatment for other diseases. Based upon this work, Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.



20. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above and became the standard of care for the treatment of chemo-induced anemia. As a result of Procrit's success, Ortho has paid Amgen over \$1.5 billion in royalties on Procrit sales.

**Aranesp**

21. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoetin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

22. Ortho's work and investment in Procrit, which demonstrated that RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

23. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp are projected to exceed \$2.8 billion in 2005.

**B. Amgen Has a Monopoly on the Sale WBCGF Drugs.**

24. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially

compromises a patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

25. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen® and Neulasta®. The only other WBCGF drug sold is Leukine®, which is distributed by Berlex Laboratories.

26. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that one injection of Neulasta is roughly equal to 7 injections of Neupogen.

27. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales. Unlike Amgen's WBCGF drugs which are administered by subcutaneous injection, Leukine must be administered intravenously – a longer and more costly process.

**C. Amgen Seeks to Monopolize the Sales of RBCGF Drugs to Oncology Clinics by Leveraging its WBCGF Drug Monopoly.**

**1. Amgen Begins Bundled Pricing on Aranesp and its WBCGF Monopoly Drugs.**

28. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

29. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Almost from the outset, Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial

amounts of Aranesp, a product that has competition. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

**2. The Early 2004 Amgen Contract**

30. Amgen's penalties became even more coercive in the spring of 2004. At that time, Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract ("APC").

31. Amgen's pricing to oncology clinics under its APC is broken into three groups – large, medium and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that once reached allows the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic's APC represent a specific percentage requirement of market share based on a clinic's historical usage. Rebates are earned when Amgen's share of the clinic's estimated total APC purchases reach those levels.

32. For example, under the APCs in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates – a 25% rebate on its Aranesp

purchases and a 25% rebate on its Amgen WBCGF drug purchases. An oncology clinic that did not meet its APCs volume requirements would only receive a minimal rebate or discount. (Examples of the rebate levels for APCs during this time frame are attached as Attachment A.)

3. **The Late 2004 Amgen Contract**

33. Later in 2004, Amgen modified its APCs. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

34. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

35. Under the modification to the APCs in late 2004, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30.0% rebate on its Aranesp purchases and a 25.0% rebate on its WBCGF drug

purchases. (Examples of the rebate levels for APCs during this time frame are attached as Attachment B.)

36. All of these changes forced a clinic to buy less Procrit and more Aranesp in order for the clinic to get access to both the WBCGF and RBCGF rebates.

37. As a result of these pricing schemes, Ortho's share of sales to oncology clinics has dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. At present, Ortho's share is estimated to be approximately 34%, with Aranesp having a 66% share.

38. This significant shift in relative market share is attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

39. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores remains at approximately 70%.

**D. Amgen's New Pricing Scheme is Designed to Eliminate Procrit from the Oncology Clinic Market.**

40. Having gained a 65% share of sales to oncology clinics by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen has now sought to tighten its squeeze on this market. Effective October 1, 2005, Amgen's pricing scheme became significantly more coercive.

41. As with the old pricing scheme, each clinic is given a series of levels of dollar volume targets for its total Amgen purchases of RBCGF and WBCGF drugs, as illustrated below for a large account<sup>1</sup>. The higher the Amgen gross purchases the higher level of rebate an oncology clinic can achieve:

Level of Amgen Purchases	Rebates		
	Aranesp	Neulasta®	Neupogen
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%
1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

42. However, to gain access to even the lowest rebate level described above an oncology clinic must now meet separate Aranesp and Neulasta dollar volume triggers. To avoid being penalized on its purchases of Amgen's dominant WBCGF drugs, the dollar volume for Aranesp purchases that an oncology clinic must achieve is now based on up to 75% of the oncology clinic's total RBCGF product purchases being Aranesp, i.e., a 75% market share.

43. A higher initial dollar volume threshold for Aranesp is only the start of this latest tying scheme. The true purpose of the new pricing scheme is to require oncology clinics to make Aranesp more than 75% of their RBCGF purchases. Under the modified APCs, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1st APC (described above), each clinic now must reach higher dollar volume (i.e., market share) levels of Aranesp. For example, for a large clinic, the top

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<sup>1</sup> Examples for medium and small accounts are set forth in Attachment C.

Aranesp rebate is now 26%. This is 4% less than under the previous Amgen bundle of 30%. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 90% as well as ensuring that Neulasta represents 90% of its WBCGF drug purchases. Thus, this new pricing scheme is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

44. The new pricing scheme also reduces the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases are of Amgen's Neulasta and the higher threshold for Amgen's Aranesp (up to 90%) is met.

45. The October 2005 addendum to the APC continues to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC does not place caps on Aranesp. This further drives oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

46. A clinic that does not meet its Aranesp volume requirement will only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is now being penalized an additional 3.1% to 5.5% on its Neulasta purchases.

**E. The Impact of this Pricing Scheme  
on an Oncology Clinic's Medicare Business.**

47. Failing to achieve a dollar volume of purchases of Aranesp roughly equivalent to a 75% market share will have severe economic consequences on an oncology clinic. Because the use of WBCGF drugs is the standard of care to treat neutropenia, oncology clinics have no choice but to carry Neulasta.



48. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula an oncology clinic would have to pay Amgen hundreds of dollars more on each treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

49. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The new formula is based on the drugs' average selling price ("ASP" as it is known in the industry) plus 6%. Thus, if a clinic bought a drug that had an ASP of \$1,000, the clinic would be reimbursed \$1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

50. As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or can not, – avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

51. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is \$2,603.00. The Medicare reimbursement (i.e., ASP plus 6%) per unit of Neulasta currently is \$2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or \$524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, a clinic must receive rebates and discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APCs. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen \$295.87 more per administration of Neulasta than the clinic is being reimbursed by the government.

52. The foregoing example is based on Neulasta's existing list price. Reportedly, Amgen is in the process of increasing the list price of Neulasta. A list price increase will result in an oncology clinic losing even more money.

53. Amgen's latest pricing scheme will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp that translate into substantial market share requirements. This will create a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked. Few oncology clinics will be able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic which wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor

relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most are in no position to take such risks.

54. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. Ortho understands that one Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme. Amgen already has nearly 65% of RBCGF drug sales in the oncology clinic market. The large scale conversion of existing Procrit accounts will effectively eliminate physician and consumer choice, as Procrit is driven out of the oncology clinic market.

**F. Ortho's Ability to Respond Competitively  
is Constrained by Amgen's Tying Arrangement.**

55. Ortho is an equally efficient competitor, and Ortho supports price competition between rival companies as the hallmark of a free market. Ortho is prepared and willing to engage in fair, head-to-head, price competition between Procrit and Aranesp. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts. That will only result in Ortho inevitably pricing below cost and in less competition.

56. As alleged in paragraph 49, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would result in

Aranesp and Procrit each having a lower ASP as the government recalculates product ASPs. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, are not, and will not be, considered as the Aranesp ASP is recalculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, i.e., 6% of a lower ASP).

57. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen is forcing Ortho to absorb on its one product the “discounts” Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it will drive the Procrit ASP down and correspondingly the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

58. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – puts Ortho at an enormous disadvantage and effectively precludes price competition. If Ortho offers a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit will be recalculated by the government at subsequent reporting intervals. (ASP's are recalculated each quarter based on pricing data from two quarters earlier.) Procrit will then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (i.e., 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen will not on Aranesp. Amgen's rebates are tied in large measure to its WBCGF drugs. Consequently, the

Aranesp ASP will not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp will force Ortho to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP remains stable because Amgen's WBCGF rebates will not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral will result in Ortho pricing Procrit below cost in order to match the Amgen's rebates on its WBCGF and RBCGF drugs.

59. It is anticipated that on January 1, 2006, the government will move hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 8%. The adoption of an ASP reimbursement system in hospitals will allow Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose competition in the sale of RBCGF drugs to oncology clinics. Amgen will again simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

**G. Procrit is a Highly Effective Drug.**

60. Procrit was the subject of extensive clinical trials demonstrating its effectiveness in the treatment of anemia and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

61. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded (1) a trend toward a lower rate of transfusion in Procrit-treated patients when

compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfused, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp treated patients.

62. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

63. Also, in May 2005 at the ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find “non-inferiority” of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

64. Finally, at the May 2005 meeting, there was a presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

## **II. Amgen’s Pricing Schemes Injure Competition.**

65. Amgen’s pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving

substantial price rebates on products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the massive rebates provided on Amgen’s dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

66. Amgen’s actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as Amgen ratchets up its leverage by implementing its latest pricing scheme.

67. This anticompetitive foreclosure has caused Ortho to lose revenue and profits that it otherwise would have earned, disrupted Ortho’s relationships with Oncology clinics, resulted in loss of good will and other harm to Ortho’s ability to innovate and compete.

68. The anti-competitive effects of Amgen’s tying and attempts to monopolize extend far beyond the substantial foreclosure of Ortho, which is Amgen’s only competitor in the sale of RBCGF drugs. There are numerous other potential uses for epoetin alfa that will likely develop in free and competitive drug markets. Without achieving a reasonable rate of return on current uses of Procrit, the ability of Ortho to fund current and future research and development projects related to alternative uses of Procrit and to seek regulatory approvals for these alternative uses is substantially



reduced. Ortho's ability to enter new markets with Procrit, either as a first mover or as a challenger to incumbents, is severely undermined by Amgen's tying and attempt to monopolize.

69. Amgen's tying arrangement would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

70. In addition, Amgen's conduct enhances and reinforces its monopoly power in the market for WBCGF drugs.

**I. Amgen's New Pricing Scheme Will  
Irreparably Harm Ortho and the Public.**

71. Amgen's latest pricing scheme is intended to foreclose Ortho from a sizeable segment of the oncology clinic market, and will embolden Amgen to take similar action in the hospital market. This development will have a devastating impact on Ortho and on patient care. Ortho will lose important longstanding customer relationships as well as the goodwill built up over the years of the Procrit franchise which has been used to treat millions of cancer patients suffering from the severe anemia that often accompanies chemotherapy. Amgen's actions will likely result in reductions in investments in ongoing research and development in order to provide better forms of treatment.

72. Eliminating Ortho as an effective competitor in the oncology clinic market will also result in less physician choice. Physicians and patients should not be effectively cut off from access to the benefits of Procrit—which many physicians would

prefer to Aranesp by virtue of Amgen's use of its monopoly leverage in the sale of WBCGF drugs.

73. If Amgen is permitted to implement its latest pricing scheme into the oncology clinic market, with the success that is envisioned and is economically predictable, Amgen will simply do the same thing in the hospital market when hospitals are reimbursed under an ASP system in January of 2006. This will compound the irreparable harm to Ortho and physicians and patients.

**J. There is No Legitimate Business Justification for Amgen's Tying Arrangement.**

74. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

**K. Sales of RBCGF Drugs to Oncology Clinics Constitute a Relevant Product Market.**

75. RBCGF drugs are sold through various channels. The roughly 2,400 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over \$2.8 billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

76. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive out-patient administration of RBCGF drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

77. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

78. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of Ortho's Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

79. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than do hospitals.

80. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

81. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the government are different than what are used for other industry participants, such as hospitals.

82. Most oncology clinics purchase drugs through entities called “specialty distributors.” Specialty distributors deliver oncology drugs, which often require careful handling (e.g., refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

83. Oncology clinics have formed their own Group Purchasing Organizations (“GPO”) to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

84. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

85. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen’s exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, and (2) secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen’s formidable patent estate.

**L. Sales of WBCGF Drugs to Oncology Clinic  
Constitute a Distinct and Separate Product Market.**

86. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.

87. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

88. Recognizing this, the Federal Trade Commission (“FTC”) stated that “the research, development, manufacture and sale of Neutrophil Regeneration Products” (a.k.a. WBCGF drugs) is a “relevant line of commerce” in a Clayton Act §7 administrative Complaint filed against Amgen and the Immunex Corporation.

89. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

90. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen’s WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen’s formidable patent estate.

### **CAUSES OF ACTION**

#### **FIRST CLAIM FOR RELIEF**

(Per Se and Rule of Reason Unlawful Tying)

91. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 90 with the same force and effect as if here set forth in full.

92. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of Section 1 of the Sherman Act, 15 U.S.C. §1. This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

93. The product characteristics, uses and character of demand for RBCGF drugs -- which are used to treat chemotherapy-induced anemia but not neutropenia -- are different from the product characteristics, uses and the character of demand for WBCGF drugs -- products that treat neutropenia, but not anemia. RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

94. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

95. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics in 2005 is projected to exceed \$2.8 billion in gross sales.

96. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs is increasingly for them to purchase all or nearly all of their RBCGF drugs from Amgen.

97. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its

product on a stand-alone basis. Amgen's pricing scheme has reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit for patients who suffer from ailments or diseases not currently treated by Epoetin Alfa.

98. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

99. Amgen's tying arrangement has adversely effected competition in the sale of RBCGF drugs to oncology clinics and will continue to do so unless enjoined.

100. As a result of Amgen's violations of Section 1 of the Sherman Act, Ortho has been injured in its business and property in an amount not presently known, but which is, at a minimum, in excess of one millions dollars, prior to trebling.

101. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

## **SECOND CLAIM FOR RELIEF**

### **(Attempt to Monopolize RBCGF Drug Market)**

102. Ortho repeats and realleges each and every allegation contained in paragraphs 1 through 100 with the same force and effect as if here set forth in full.

103. In violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, Amgen has willingly, knowingly, intentionally and with specific intent to do so, attempted to monopolize sales of RBCGF drugs to oncology clinics.

104. This attempt to monopolize has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:



- conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from defendant;
- granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from defendant.

105. There is a dangerous probability that Amgen, by using these exclusionary practices, will monopolize the sale of RBCGF drugs to oncology clinics.

106. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to oncology clinics. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition on the merits from Ortho in the sale of RBCGF drugs to oncology clinics and other customers. Amgen's conduct will also raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs. Amgen's conduct has also reduced and will continue to reduce the ability and incentive for Ortho to work toward new applications for Procrit to benefit patients who suffer from ailments or diseases not currently treated with Epoetin Alfa.

107. Amgen intends to take further acts aimed specifically at further foreclosing competition in the sale of RBCGF drugs to oncology clinics.

108. There is no legitimate business justification or pro-competitive benefit from Amgen's exclusionary practices.

109. As a result of Amgen's violations of Section 2, Ortho has been injured in its business and property in an amount not presently known but which is, at a minimum, in excess of one millions dollars prior to trebling.

110. Such violation and the effects thereof are continuing and will continue unless injunctive relief is granted. Ortho has no adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Ortho Biotech Products, L.P. respectfully requests the following relief:

A. That the Court declare, adjudge and decree that Defendant Amgen Inc. has committed the violations of federal law alleged herein;

B. That the Court enter a preliminary and permanent injunction enjoining Amgen Inc. from employing its latest pricing scheme, which began effective October 1, 2005, and any comparable pricing scheme that achieves the same result of coercing oncology clinics to purchase substantial amounts of Aranesp as a condition of access to substantial discounts on Amgen's WBCGF drugs;

C. That Amgen Inc., its directors, officers, employees, agents, successors, and assigns be permanently enjoined and restrained from, in any manner, directly or indirectly conditioning the sale or discounts on the sale of WBCGF drugs on the purchase of RBCGF drugs or any other conduct which has the same purpose or effect, and committing any other violations of Sections 1 and 2 of the Sherman Act described herein and that Amgen, its directors, officers, employees, agents, successors and assigns be enjoined and restrained from, in any manner, directly or indirectly, committing any other violations of the antitrust laws or statutes having a similar purpose or effect; and

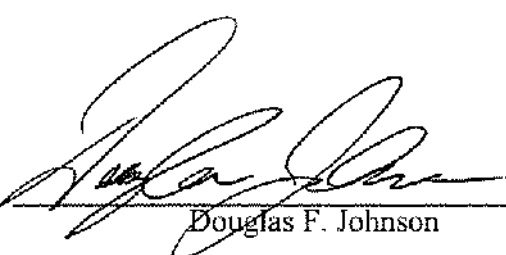
D. That the Court award to Plaintiff Ortho Biotech Products, L.P. the damages it has sustained as a result of the illegal conduct of Defendant Amgen Inc., in an amount to be proved at trial, to be trebled according to law, plus interest (including prejudgment interest), attorneys' fees and costs of suit, and such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Ortho hereby demands trial by jury of all issues properly triable thereby.

Dated: Trenton, New Jersey  
October 11, 2005

By: \_\_\_\_\_

  
Douglas F. Johnson

**EARP COHN P.C.**

20 Brace Road, 4th Floor  
Cherry Hill, NJ 08034  
(856) 354-7700  
(856) 354-0766 Facsimile

**PATTERSON BELKNAP WEBB  
& TYLER LLP**

William F. Cavanaugh, Jr.  
Erik Haas  
Jeffrey D. Rotenberg  
Wendy Kemp Akbar  
1133 Avenue of the Americas  
New York, New York 10036  
(212) 336-2000  
(212) 336-2222 Facsimile

and

**CONSTANTINE CANNON PC**

Lloyd Constantine  
Matthew L. Cantor  
Reiko Cyr  
Axel Bernabe  
450 Lexington Avenue  
New York, New York 10017  
(212) 350-2700  
(212) 350-2701 Facsimile

*Attorneys for Plaintiff  
Ortho Biotech Products, L.P.*

**ATTACHMENT A**

Large Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	25.00%	25.00%
	80%	20.00%	20.00%
	75%	18.50%	13.50%
	70%	14.5%	11.50%
	65%	13.5%	10.50%
	55%	11.5%	7.5%
	50%	5%	5%

Medium Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	20.00%	21.00%
	80%	18.00%	16.00%
	75%	16.50%	12.50%
	70%	13.5%	10.50%
	65%	12.5%	9.50%
	55%	10.5%	6.5%
	50%	4%	4%

Small Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	16.00%	16.00%
	80%	14.00%	14.00%
	75%	12.00%	11.50%
	70%	11.00%	9.50%
	65%	10.00%	8.50%
	55%	8.50%	5.50%
	50%	3%	3%

**ATTACHMENT B**

Large Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	30.00%	25.00%
	80%	25.00%	20.00%
	75%	23.50%	13.50%
	70%	19.5%	11.50%
	65%	18.5%	10.50%
	55%	11.5%	7.5%
	50%	5%	5%

Medium Account:

Tier – combined		Rebate	
	Share of Amgen RBCGF and WBCGF Drugs over estimated total purchases	Aranesp	Neupogen/Neulasta
	85%	25.00%	21.00%
	80%	23.00%	16.00%
	75%	21.50%	12.50%
	70%	18.5%	10.50%
	65%	17.5%	9.50%
	55%	10.5%	6.5%
	50%	4%	4%

Small Account:

Tier – combined		Rebate	
	Share of RBCGF and WBCGF Drugs	Aranesp	Neupogen/Neulasta
	85%	21.00%	16.00%
	80%	19.00%	14.00%
	75%	17.00%	11.50%
	70%	16.00%	9.50%
	65%	15.00%	8.50%
	55%	8.50%	5.50%
	50%	3%	3%

**ATTACHMENT C**

Medium Account:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	21.0%	17.0%	16.0%
5	20.5%	16.5%	15.0%
4	20.0%	16.0%	14.0%
3	19.5%	15.5%	13.0%
2	19.0%	15.0%	12.0%
1	18.5%	14.5%	11.0%
base level	18.0%	14.0%	10.0%

Small Account:

	Rebates		
	Aranesp®	Neulasta®	Neupogen®
Level of Amgen Purchases			
6	18.00%	12.00%	11.00%
5	17.50%	11.50%	10.00%
4	17.00%	11.00%	9.00%
3	16.50%	10.50%	8.00%
2	16.00%	10.00%	7.00%
1	15.50%	9.50%	6.00%
base level	15.00%	9.00%	5.00%



# EXHIBIT F

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

SHEET METAL WORKERS NATIONAL  
HEALTH FUND, individually and on behalf of  
all others similarly situated,

Plaintiff,

v.

AMGEN INC. and AMGEN USA INC.,

Defendants.

CASE NO.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Sheet Metal Workers National Health Fund (“SMW Health Fund”), by its undersigned attorneys, hereby make the allegations in this Class Action Complaint against Defendants Amgen Inc. and Amgen USA Inc., (collectively, “Amgen” or “Defendants”) concerning their acts and status upon actual knowledge, and concerning all other matters upon information, belief, and the investigation of their counsel:

**I. SUMMARY OF CLAIMS**

1. This antitrust action, brought under federal and state antitrust law, involves an anti-competitive tying arrangement and pricing scheme implemented by Amgen in the oncology clinic market. The scheme ties substantial purchases of Amgen’s Red Blood Cell Growth Factor (“RBCGF”) drug to its dominant White Blood Cell Growth Factor (“WBCGF”) drugs. Both WBCGF and RBCGF drugs are needed by oncology clinics to treat cancer patients. The purpose of Amgen’s scheme was and is to restrain competition and monopolize the market for sales of RBCGF drugs to oncology clinics. The result has been, and will continue to be, less price competition, less physician and patient choice and an increased expense to the public health system, including an increased price to Plaintiff and members of the Class who pay for or reimburse for treatment at oncology clinics.

2. Ortho sells Procrit. Amgen sells Aranesp. Both are RBCGF drugs that, prior to the implementation of Amgen's scheme, competed head-to-head in a two-player market. Annual combined sales to oncology clinics of these two products exceeded \$2.8 billion in 2005.

3. Amgen also sells Neulasta and Neupogen, which are WBCGF drugs with a combined 98% market share of sales to oncology clinics. Amgen has a monopoly in the market for WBCGF drugs. Ortho does not sell a WBCGF drug.

4. Amgen's illegal pricing scheme penalizes oncology clinics on purchases of its monopoly WBCGF drug if the clinics do not purchase significant volumes of Amgen's Aranesp instead of Ortho's Procrit. From its inception in April 2004 through October 2005, Amgen's illegal pricing scheme caused Aranesp share to increase by 46%, to approximately 66% of the oncology clinic RBCGF drug market. Its market share has continued to increase.

5. On October 1, 2005, Amgen's pricing scheme became considerably more coercive and further restrained price competition in the RBCGF market. Amgen imposed, and continues to impose, even steeper pricing penalties on Amgen's monopoly WBCGF drugs when oncology clinics do not purchase 75% or more of their RBCGF drugs from Amgen. In fact, for a clinic to receive the same level of RBCGF and WBCGF drug rebates it received under the pre-October 1, 2005 contract, it had to increase its Aranesp share well above that amount.

6. Amgen's pricing scheme puts oncology clinics in a completely untenable position. A clinic will end up losing several hundred dollars per administration of Amgen's leading WBCGF drug because the cost of buying the drug (absent the contractual rebates) vastly exceeds the amount of government reimbursement. ***A clinic can only gain access to the rebates on Amgen's monopoly WBCGF drugs when it purchases virtually all of its RBCGF drug requirements from Amgen.***

7. Defendants' conduct constitutes a tying arrangement and/or restraint of trade in violation of federal and state antitrust law under either a *per se* or Rule of Reason analysis. As the result of Amgen's restraint of trade, Amgen's pricing scheme leaves oncology clinics with no economic alternative but to purchase virtually all RBCGF drugs from Amgen. The effect of this is to cause physicians to use Aranesp instead of the lower cost Procrit, which in turn raised the price to end payers – Plaintiff, other third-party payers and consumers.

8. Limiting payers' and clinics' access to Procrit is not in the public interest and has and will continue to harm payers and consumers. Physicians should not face economic coercion, and the healthcare system should not bear the increased costs of that coercion. Forcing oncologists to abandon the lower cost Procrit as the only economically viable way to gain access to another potentially life saving drug, is not, by any measure, in the public interest.

9. For these reasons, and to remedy the injuries that will be caused and have been caused by Amgen's anticompetitive conduct, Plaintiff seeks injunctive relief as well as treble damages.

## II. JURISDICTION AND VENUE

10. This Court has personal jurisdiction over this lawsuit because Defendants have sufficient contacts with New Jersey to permit the exercise of jurisdiction in compliance with traditional notions of fair play and substantial justice. Defendants have offices in New Jersey, transact business in New Jersey, employ New Jersey residents, and hold memberships in New Jersey organizations and associations. Also, the acts complained of herein have substantial anticompetitive effects in this district.

11. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds \$5,000,000 exclusive of interest and costs, and is a class action in which some members

of the Class are citizens of states different than Defendant. *See* 28 U.S.C. § 1332(d)(2)(A).

Also, 28 U.S.C. §§ 1331, 1337, 2201 and 2002 give this Court subject-matter jurisdiction over Plaintiff's claims for violation of the Clayton Act, 15 U.S.C. § 26 and the Sherman Act, 15 U.S.C. §§ 1-2.

12. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(2) and 15 U.S.C. §§ 15, 22 and 26, because Defendants have offices in New Jersey and transact business in New Jersey, and because acts or omissions giving rise to the claims set forth here occurred in and near this judicial district. Venue is also proper in this judicial district under L. Civ. R. 40.1(c), because this action is related to a case currently pending in this Court, *Ortho Biotech Products, L.P. v. Amgen, Inc. and Amgen USA, Inc.*, Civil Action No. 05-04850 (SRC-MF).

### III. THE PARTIES

13. Plaintiff SMW Health Fund is a Taft-Hartley trust administered pursuant to the requirements of 29 U.S.C. § 186 by an equal number of trustees appointed by labor and union representatives. SMW Health Fund is a multiemployer welfare fund subject to ERISA. SMW Health Fund's office is located in Goodlettsville, Tennessee. At all relevant times, SMW Health Fund paid reimbursements for Aranesp administered in oncology clinics across the country.

14. Defendants Amgen Inc. and Amgen USA Inc. are corporations organized and existing under the laws of Delaware with their principal places of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen, among other things, manufactures and sells Aranesp as well as two WBCGF drugs, Neupogen and Neulasta.

#### IV. FACTUAL ALLEGATIONS

##### A. Ortho And Amgen Are The Only Competitors In The Sale Of RBCGF Drugs To Oncology Clinics Where Consumer Class Members Are Treated

###### 1. Procrit

15. Severe anemia is most commonly seen in patients: (1) with chronic kidney disease either pre-dialysis or while undergoing dialysis, (2) undergoing chemotherapy, or (3) undergoing zidovudine treatment for HIV disease. Anemia is caused by the depletion of the human hormone erythropoietin, which is produced primarily by the kidneys and stimulates red blood cell production and maturation in the bone marrow. Chemotherapy, for example, depresses erythropoietin production, often leading to anemia. Many patients suffering from anemia cannot lead normal, productive lives.

16. Epoetin alfa is a synthetic form of erythropoietin that stimulates the production of red blood cells and is often referred to as a RBCGF drug. Prior to the introduction of epoetin alfa drugs, the treatment for more severe cases of anemia was whole blood or red blood cell transfusions.

17. Ortho sells Procrit, a branded version of epoetin alfa. By the Product License Agreement (“PLA”) executed as of September 30, 1985, Amgen granted Ortho an exclusive license under Amgen’s patents to market and sell epoetin alfa in the United States for anemia in humans resulting from all treatments except anemia in patients undergoing dialysis for end stage renal disease (“ESRD”). Under the PLA, Amgen retained the right to market an epoetin alfa product for humans in this one field, which it does under the brand name Epogen.

18. Ortho secured FDA approvals, beginning in 1991, to market Procrit for the treatment of persons who develop anemia as a consequence of: (1) chemotherapy for cancer, (2) treatment of HIV infection with the pharmaceutical zidovudine, (3) chronic kidney diseases

in pre-dialysis patients, and (4) in anemic patients scheduled to undergo elective, noncardiac, nonvascular surgery.

19. Since Procrit was launched in 1991, it has been prescribed to millions who suffer from anemia included in the four indications listed above. As a result of Procrit's success, Ortho has paid Amgen over \$1.5 billion in royalties on Procrit sales.

## **2. Aranesp**

20. Amgen decided to circumvent the market exclusivity it had granted to Ortho to sell epoetin alfa for all purposes other than dialysis. The result was Amgen's introduction of Aranesp, a synthetic form of erythropoietin known as darbepoetin alfa. It was formulated by modifying the epoetin alfa molecule, thereby circumventing the exclusive rights granted to Ortho on epoetin alfa. In 2002, Amgen received regulatory approval to sell Aranesp, a branded RBCGF drug, to treat chemo-induced anemia.

21. Ortho's work and investment in Procrit, which demonstrated the RBCGF drugs could be safely, effectively and widely used to combat chemo-induced anemia, helped Amgen to secure FDA approval of Aranesp and to sell Aranesp into markets in which physicians had been educated by Ortho about the benefits of RBCGF drugs.

22. Given the scope of Amgen's patents, Ortho and Amgen are the only two competitors for the sale of RBCGF drugs to treat chemo-induced anemia in the United States. Gross sales to oncology clinics for Procrit and Aranesp exceeded \$2.8 billion in 2005.

## **B. Amgen Has A Monopoly On The Sale WBCGF Drugs**

23. Many cancer patients undergoing chemotherapy may, for different reasons, also require a WBCGF drug to combat neutropenia, a white blood cell deficiency that is potentially life threatening. Neutropenia is a side effect of chemotherapy which potentially compromises a



patient's immune system. The disease occurs not only in many patients undergoing chemotherapy, but in individuals suffering from a number of other diseases.

24. Ortho does not sell a WBCGF drug, but Amgen does. Amgen sells two WBCGF drugs, Neupogen and Neulasta. The only other WBCGF drug sold is Leukine, which is distributed by Berlex Laboratories.

25. Neupogen was Amgen's initial WBCGF drug. In 2002, Amgen introduced Neulasta, a WBCGF product, which has been modified so that, according to Amgen, one injection of Neulasta is roughly equal to seven injections of Neupogen.

26. Amgen dominates the sales of WBCGF drugs which have become the recognized standard of care for the treatment of neutropenia. Amgen has a 98% share of the sales to oncology clinics (with Neulasta alone having an 86% market share). Although Berlex's Leukine product has been on the market for many years, it has only a *de minimus* share of WBCGF sales.

**C. Amgen Has Monopolized The Sales Of RBCGF Drugs To Oncology Clinics By Leveraging Its WBCGF Drug Monopoly**

**1. Amgen begins bundled pricing on Aranesp and its WBCGF monopoly drugs**

27. Virtually all oncology clinics administer both RBCGF and WBCGF drugs to patients. Given this fact and Amgen's monopoly on WBCGF drugs, these clinics must buy WBCGF drugs, particularly Neulasta, from Amgen.

28. This fact was not lost on Amgen as it developed a marketing plan for Aranesp. Amgen's strategy for selling Aranesp has been to penalize a clinic on the pricing of its dominant WBCGF drugs if the clinic did not purchase substantial amounts of Aranesp. The volume requirements in Amgen's pricing schemes for its RBCGF and WBCGF drugs are, in fact, disguised market share requirements designed to reduce Procrit's share of clinic sales by means other than competition on the price of RBCGF drugs or their relative merits.

## 2. The early 2004 Amgen contract

29. Amgen implemented the coercive pricing scheme at issue in the spring of 2004. At that time, Amgen began offering substantial “rebates” to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen’s RBCGF and WBCGF drugs. Amgen refers to these offerings on its RBCGF and WBCGF drugs as the Amgen Portfolio Contract (“APC”).

30. Amgen’s pricing to oncology clinics under its APC is broken into three groups – large, medium and small accounts – based on the amount of RBCGF and WBCGF drugs purchased. Each account is given dollar volume usage targets that, once reached, allow the clinic to earn a specified level of rebate. The dollar volume targets Amgen puts in each clinic’s APC represent a specific percentage requirement of market share based on that clinic’s historical usage. Rebates are earned when Amgen’s share of the clinic’s estimated total APC purchases reach those levels.

31. For example, under the APC in effect in the first half of 2004, a large account oncology clinic which purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen received a 13.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen received significantly greater rebates – a 25% rebate on its Aranesp purchases and a 25% rebate on Amgen’s WBCGF drug purchases. An oncology clinic that did not meet its APC volume requirements would only receive a minimal rebate or discount.

## 3. The January 1, 2005 Amgen contract

32. Effective January 1, 2005, Amgen modified its APC. Amgen apparently recognized that simply providing an oncology clinic with a combined dollar volume target might

give the clinic the flexibility of loading up on Amgen's WBCGF drugs to meet its combined dollar volume target, rather than shifting its Procrit purchases to Aranesp. As a result, Amgen imposed restrictions on the amount of WBCGF drugs that could be considered for purposes of reaching the specified dollar volume targets or higher rebate levels. This forced oncology clinics to purchase more Aranesp, which was not subject to any incentive restrictions to reach higher rebate levels.

33. Amgen also required minimum dollar volume requirements for Aranesp. In addition, Amgen increased the rebates offered to oncology clinics, further penalizing those oncology clinics that failed to meet the dollar volume requirements set forth in each clinic's APC. With these changes to the APC, Amgen sought to more closely tie the rebates on its monopoly WBCGF drugs to the purchase of substantial amounts of Aranesp.

34. Under the revised APC, a large oncology clinic that purchased roughly 65% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive an 18.5% rebate on its Aranesp purchases and a 10.5% rebate on its WBCGF drug purchases. However, an oncology clinic that purchased roughly 85% of its combined volume of RBCGF and WBCGF drugs from Amgen would receive a 30% rebate on its Aranesp purchases and a 25% rebate on its WBCGF drug purchases.

35. All of these changes forced clinics to buy less Procrit and more Aranesp in order to get access to **both** the WBCGF and RBCGF rebates.

36. As a result of these pricing schemes, Ortho's share of sales to oncology clinics dropped precipitously. In the first quarter of 2004, Ortho had a 55% share of the oncology clinic market for RBCGF drugs and Amgen had a 45% share. By October 2005, Ortho's share had dropped to approximately 34%, with Aranesp having a 66% share.

37. This significant shift in relative market share was attributable to oncology clinics being coerced by Amgen to replace substantial volumes of Procrit with Aranesp in order for these customers to gain access to acceptable pricing on the WBCGF drugs they must buy from Amgen.

38. The effect of Amgen's coercive tying arrangements on sales of RBCGF drugs to oncology clinics is evidenced by comparing Procrit and Aranesp market shares to oncology clinics with their respective share of sales in another market – sales to retail drug stores – where Amgen has not introduced these tying arrangements. As a result, Procrit and Aranesp compete head to head without interference from Amgen's WBCGF monopoly drugs. Procrit's share of sales to retail drug stores was, and remains at, approximately 70%.

**D. Amgen's New Pricing Scheme Is Designed To Eliminate Procrit From The Oncology Clinic Market**

39. Having gained a 65% share of oncology clinic sales by tying access to WBCGF drug rebates to substantial purchases of Aranesp instead of Procrit, Amgen knew that it could further tighten its squeeze on this market. On October 1, 2005, Amgen's pricing scheme became significantly more coercive.

40. As with the previous pricing schemes, Amgen gave each clinic a series of dollar volume target levels for its total purchases of RBCGF and WBCGF drugs. As illustrated below for a typical large account, the more a clinic purchased, the greater rebate it received:

	Rebates		
	Aranesp	Neulasta®	Neupogen
Level of Amgen Purchases			
6	26.0%	21.0%	20.0%
5	25.5%	20.5%	19.0%
4	25.0%	20.0%	18.0%
3	24.5%	19.5%	17.0%
2	24.0%	19.0%	16.0%

1	23.5%	18.5%	15.0%
base level	23.0%	18.0%	14.0%

41. However, to gain access to even the lowest rebate level described above an oncology clinic was required to meet separate Aranesp and Neulasta dollar volume triggers. The threshold for Aranesp was set at dollar amounts equal to 65% of a clinic's prior RBCGF drug purchases (*i.e.*, 65% market share requirement), while the threshold for Neupogen and Neulasta was set at up to 100% of a clinic's prior purchases. Thus, to earn the minimum rebates required to avoid a loss on the administration of the WBCGF drugs to Medicare patients, a clinic has to buy Aranesp for at least 65% of its total RBCGF purchases.

42. A higher initial dollar volume threshold for Aranesp was only the start of the October 2005 pricing scheme. The scheme also was intended to coerce oncology clinics to purchase Aranesp for more than the minimum market share requirements. Under the modified APC, for an oncology clinic to receive the same aggregate value it had been receiving while performing under the pre-October 1, 2005 APC (described above), each clinic was required to purchase larger volumes of Aranesp in order to reach the higher levels of the rebate schedules. Moreover, the clinic's Aranesp purchases had to amount to at least 75% of its total RBCGF drug purchases to be eligible for the same level of rebates previously received. For example, for a large clinic, the top Aranesp rebate was 26%. This was 4% less than under the previous Amgen bundle, where a clinic could receive a 30% rebate. However, the clinic can earn back the additional 4% by taking its Aranesp share up to 75%. Thus, the 2005 pricing scheme was and is intended to raise the Aranesp levels well above the initial threshold number needed to qualify for any rebate.

43. This pricing scheme also reduced the highest Neulasta rebate from 25% to 21% for large clinics. As with the Aranesp rebates, an oncology clinic can earn back the 4% on Neulasta if 90% of its WBCGF drug purchases were of Amgen's Neulasta **and** the higher threshold for Amgen's Aranesp (up to 90%) was met.

44. The October 2005 pricing scheme continued to place limits on the amount of the WBCGF drugs that may be considered for purposes of determining rebate levels on gross purchases. Conversely, the APC did not place caps on Aranesp. This further drove oncology clinics to purchase all or substantially all of their RBCGF drugs from Amgen.

45. A clinic that did not meet its Aranesp volume requirement would only receive a 4% rebate on Neulasta. Previously, an oncology clinic that did not meet its Aranesp dollar volume target requirements in its APC nonetheless would receive a rebate of 7.1% to 9.5% on Neulasta. Thus, a non-conforming oncology clinic is being penalized an additional 3.1% to 5.5% on its Neulasta purchases under the October 2005 APC.

## E. The Impact Of This Pricing Scheme On An Oncology Clinic's Medicare Business

46. Failing to meet the minimum Aranesp purchase requirements in the revised APC had severe economic consequences for oncology clinics. Because the use of WBCGF drugs had been established as the standard of care for treating neutropenia, oncology clinics had no choice but to carry Neulasta.

47. Medicare patients make up roughly 40% of the patient population treated in oncology clinics. As such, the economics of treating this patient group is a major consideration for any clinic. Without the Neulasta rebates (up to 25%), under the government's current reimbursement formula, an oncology clinic would have to pay Amgen hundreds of dollars more on treatment of Neulasta for a Medicare patient than the clinic will receive in reimbursement from the government and patients.

48. On January 1, 2005, the federal government changed the formula by which doctors and clinics are reimbursed for the drugs they purchase and administer in their offices. The formula is based on the drugs' average selling price ("ASP") plus 6%. Thus, if a clinic bought a drug that had an ASP of \$1,000, the clinic would be reimbursed \$1,060. This reimbursement amount is static regardless of what the particular clinic actually paid for the drug. The "plus 6%" is not intended to be profit to an oncology clinic. It is to provide the clinic with some cover on costs associated with the acquisition and storage of the drug, other costs associated with purchasing expensive drugs that require refrigeration, and bad debt from patients who do not make co-pays.

49. As the term suggests, the ASP of a drug is an average based on the prices paid – and discounts and rebates earned – by all purchasers of such drugs. Accordingly, a Medicare provider that does not, or cannot avail itself of all of the rebates offered by a manufacturer can end up paying the manufacturer more for the drug than the drug's ASP and even more than the amount the provider will be reimbursed by the government (ASP + 6%). Where the price paid exceeds the reimbursement amount, the provider actually realizes a loss on the acquisition of a particular drug.

50. Unless an oncology clinic qualifies for Amgen's rebates, this is precisely the situation the clinic will face when it administers Neulasta, Amgen's dominant WBCGF product, as the following example illustrates: Neulasta's list price is \$2,603.00. The Medicare reimbursement (*i.e.*, ASP + 6%) per unit of Neulasta was \$2,078.066 in 4th quarter 2005 as published by the Centers for Medicare and Medicaid Services ("CMS"). That amount is 20.17% or \$524.93 below Neulasta's list price due to the rebates and incentives previously granted by Amgen. Thus, to break even on a per treatment basis, the clinic had to receive rebates and



discounts equal to 20.17% below Amgen's list price. Amgen currently provides oncology clinics with just a 5% discount off list price and a 4% rebate if the clinics fail to buy the requisite levels of Aranesp specified in their modified APC. In other words, unless the clinics meet the Aranesp volume requirements, the clinic will pay Amgen \$295.87 more *per administration* of Neulasta than the clinic is being reimbursed by the government.

51. The foregoing example is based on Neulasta's list price as of October 2005. Amgen has since increased the list price of Neulasta, which would result in oncology clinics losing even more money if they fail to meet Amgen's purchase requirements.

52. Amgen's latest pricing scheme has forced and will force oncology clinics to attempt to meet Amgen's enhanced dollar volume requirements for Aranesp, which translate into substantial market share requirements. This creates a strong incentive on the part of the oncology clinic to stock only Aranesp, or to reduce dramatically the level of Procrit stocked, and ultimately to harm competition and raise prices paid by end payers. Few oncology clinics are able to bear the cost and financial risk of also stocking Procrit given the level of Amgen's dollar volume requirements for Aranesp. An oncology clinic that wanted to use even a small amount of Procrit would need to stock both Procrit and Aranesp but would have to carefully manage and monitor relative usage of Aranesp and Procrit, with severe financial consequences should it err in this process. Most oncology clinics are in no position to take such risks.

53. Amgen's current efforts to leverage its monopoly in the WBCGF drug market by penalizing oncology clinics that do not buy substantial amounts of Aranesp, coupled with the Medicare reimbursement regime, preclude Ortho from competing over the long-term in the RBCGF oncology clinic market. One Amgen official already has boasted to a Procrit customer that they expect 75% of existing Procrit customers will agree to Amgen's latest pricing scheme.

Amgen had secured nearly 65% of RBCGF drug sales in the oncology clinic market before implementing its latest version of the APC. Amgen's coercive revisions have enabled it to increase and maintain its monopoly share in the RBCGF drug oncology clinic market.

**F. Ortho's Ability To Respond Competitively Is Constrained By Amgen's Tying Arrangement**

54. Ortho is an equally efficient competitor. But given the way in which government reimbursement works for a large percentage of a clinic's patients, Amgen's scheme of tying rebates on its monopoly drug to purchases of its RBCGF drug effectively precludes Ortho from responding with commensurate price cuts, causing Plaintiff to pay higher prices for RBCGF drugs.

55. As alleged above, the government's reimbursement formula for Medicare patients for Procrit and Aranesp is based on each product's ASP plus 6%. Absent Amgen's tying arrangements in which WBCGF rebates are tied to Aranesp purchases, price competition between Aranesp and Procrit (in the form of discounts or rebates) would have resulted in Aranesp and Procrit each having a lower ASP as calculated by the government. Here, the rebates provided on Neulasta, while tied by Amgen to an oncology clinic buying a certain volume of Aranesp, have not been, and will not be, considered as the Aranesp ASP is calculated by the government. As a result, offering Neulasta rebates tied to Aranesp purchases allows Amgen to make it financially attractive to buy Aranesp, but in a way which avoids the corresponding effect of a lower Aranesp ASP (which, in turn, provides an oncology clinic with a smaller cushion, in dollar terms, on reimbursement for Aranesp, *i.e.*, 6% of a lower ASP).

56. Put simply, by tying together rebates on WBCGF drugs with purchases of Aranesp, Amgen forces Ortho to absorb on its one product the discounts Amgen has spread over two products. The result of Ortho having to absorb discounts on its one product, Procrit, is that it

will drive Procrit ASP down and, correspondingly, the level of government reimbursement on Procrit. Because, however, the WBCGF rebates are a disguised way of discounting Aranesp, the Aranesp ASP will not go down correspondingly.

57. The lack of parity in the lowering of the ASPs of Procrit and Aranesp – because of the Amgen tie – effectively precludes price competition. If Ortho were to offer a discount on Procrit commensurate with discounts offered by Amgen on its WBCGF and RBCGF drugs, a lower ASP for Procrit would be recalculated by the government at subsequent reporting intervals. (ASP's are recalculated each quarter based on pricing data from two quarters earlier.) Procrit would then have to offer an additional discount on the lower ASP because an ASP plus 6% reimbursement on a lower ASP provides the clinic with less money to cover its costs (*i.e.*, 6% of a lower ASP). While Ortho would be required to make up the difference in dollars to oncology clinics under a lower Procrit ASP, Amgen would not on Aranesp. Amgen's rebates are tied to its WBCGF drugs and, therefore, Amgen could match any incremental margin created by Procrit discounting with incremental incentives on its WBCGF drugs. Consequently, the Aranesp ASP would not drop to the same extent as Procrit's. The result of Procrit having a lower ASP than Aranesp is that Ortho would be forced to continue to chase Procrit's ASP down – each drop in the Procrit ASP will require an additional discount on the lower ASP to make up the dollar discount to oncology clinics to cover their costs. Meanwhile, the Aranesp ASP has remained and would remain stable because Amgen's WBCGF rebates do not affect the Aranesp ASP, although they are tied to and driving Aranesp sales. The Procrit price spiral would result in Ortho pricing Procrit below cost in order to match Amgen's rebates on its WBCGF and RBCGF drugs.

58. On January 1, 2006, the government moved hospital reimbursement for Medicare outpatients to an ASP reimbursement system. Hospitals reportedly will be reimbursed at ASP plus 6%. The adoption of an ASP reimbursement system in hospitals allows Amgen to introduce into hospitals the same pricing scheme it is now using to foreclose price competition in the sale of RBCGF drugs to oncology clinics. Amgen may, again, simply leverage its monopoly in WBCGF drugs to provide, in effect, rebates on Aranesp without impacting the Aranesp ASP.

**G. Procrit Is A Highly Effective Drug**

59. Extensive clinical trials have repeatedly demonstrated Procrit's effectiveness in the treatment of anemia, and millions of Americans have been administered Procrit over the past 14 years. Recent studies and reports continue to underscore Procrit's efficacy.

60. In May 2005, the results of a comparative clinical trial involving Aranesp and Procrit designed specifically to measure the rate of hemoglobin improvement were presented at the annual meeting of the American Society of Clinical Oncology ("ASCO"). The study authors, led by Dr. Roger Waltzman of Saint Vincent's Comprehensive Cancer Center, concluded: (1) a trend toward a lower rate of transfusion in Procrit-treated patients when compared to Aranesp-treated patients, and (2) a significant difference between treatments in the total number of red blood cell units transfused, with Procrit-treated patients requiring far fewer units per patient transfused than Aranesp-treated patients.

61. Aside from the expense, time and invasive nature of the procedure, transfusions present numerous medical risks. Chemotherapy patients are significantly benefited by a reduction in the number of transfusions and the amount of blood transfused, as is the health care system as a whole since the available blood supply for emergency use in other patients is not otherwise depleted.

62. At the May 2005 ASCO meeting, there was a presentation on a comparative study of Procrit and Aranesp sponsored by Amgen and led by Dr. John Glaspy of the University of California at Los Angeles. The study was designed to find “non-inferiority” of either product if the level of transfusions fell within a broad range. Having defined equivalence in these broad terms, the study concluded that Procrit and Aranesp were not inferior to one another.

63. At the May 2005 ASCO meeting, there was another presentation based on an independent, retrospective chart review conducted by Dr. A.S. Case with the University of Alabama at Birmingham. The review was directed at determining the transfusion rates after treatment with Procrit and Aranesp. Based on this observational data, the authors found that a significantly lower proportion of patients required transfusions, and fewer total units were transfused, when treated with Procrit rather than Aranesp.

#### **H. Amgen’s Pricing Schemes Have Injured Plaintiff And Competition As A Whole**

64. Amgen’s pricing schemes have caused and will continue to cause anti-competitive effects in the relevant product markets. Amgen economically coerces oncology clinics to purchase its RBCGF product, Aranesp, as a condition for receiving substantial price rebates and products that they must purchase from Amgen – WBCGF drugs. Unless they purchase significant amounts of their RBCGF drugs from Amgen, oncology clinics will not qualify for the massive rebates provided on Amgen’s dominant WBCGF drugs. Moreover, if they agree to buy virtually all of their RBCGF and WBCGF drugs from Amgen, oncology clinics are given even higher rebates. The only economically viable option for these oncology clinics is to purchase all or nearly all of their RBCGF drugs from Amgen, even though many physicians would prefer Procrit if Aranesp competed head-to-head with Procrit.

65. Amgen's coercive bundling programs have caused public and private health care insurers, including third-party payer members of the Class, to reimburse clinics for their Aranesp purchases at rates that are higher than would have prevailed in "head-to-head" competition.

66. Moreover, Amgen's actions substantially foreclose Ortho from selling Procrit to oncology clinics. This foreclosure is demonstrated by the significant market share shift that has occurred and will continue to occur as a result of Amgen's latest pricing scheme.

67. Amgen's tying arrangement and restraint of trade would also require potential RBCGF drug competitors to price their product below any true measure of cost in the pharmaceutical industry, even if these potential competitors were as efficient as Amgen. In this manner, Amgen's tying arrangement has caused and will continue to cause anticompetitive effects by increasing the barriers to entry into RBCGF drug markets.

**I. There Is No Legitimate Business Justification For Amgen's Tying Arrangement Or Its Pricing Scheme**

68. There is no legitimate business purpose or efficiency justification for Amgen's pricing schemes. Amgen has employed these schemes for the sole purpose of eliminating Ortho and potential entrants as competitors in the sale of RBCGF drugs to oncology clinics.

**J. Sales Of RBCGF Drugs To Oncology Clinics Constitute A Relevant Product Market**

69. RBCGF drugs are sold through various channels. The roughly 2,300 oncology clinics in the United States represent the largest market for Procrit and Aranesp, with over \$3.8 Billion in gross sales projected in 2005. "Oncology clinics" include the small number of "mixed use" clinics that provide oncology as well as other clinic services.

70. To be successful, a seller of RBCGF drugs must have a strong presence in oncology clinics. These clinics, which are often owned and operated by oncologists in private practice, are the preferred venue for patients to receive outpatient administration of RBCGF

drugs as well as WBCGF drugs. At present, the vast majority of outpatient administration of RBCGF drugs occurs in oncology clinics.

71. Both Amgen and Ortho have historically treated oncology clinics as a distinct market. Amgen and Ortho participate in audits of epoetin alfa sales designed to align dialysis (Epogen) and non-dialysis Procrit sales in accordance with the license. The audit methodology was formulated by Amgen. It treats oncology clinics as a distinct market segment because oncology clinics use RBCGF drugs exclusively to treat anemia associated with non-dialysis indications. Because the non-dialysis indications belong to Ortho under the PLA, the audit treats all sales to oncology clinics of both parties' brands of epoetin alfa (Epogen or Procrit) as belonging to Ortho.

72. Amgen and Ortho have also recognized oncology clinics as a distinct market in their pricing. The pricing scheme that is the subject of this Complaint is being offered only to oncology clinics, and Amgen has used this distinction in other pricing programs. For instance, in the past, Amgen offered hospitals 30% "off invoice" discounts for the purchase of Aranesp, but did not offer oncology clinics this favored "off invoice" pricing.

73. An analysis of prices for Procrit shows that oncology clinics on average pay roughly 5% more for the drug than hospitals do.

74. Hospitals cannot buy more RBCGF drugs than they need and "arbitrage" a portion of their purchases by reselling to oncology clinics. It has been a longstanding practice in the pharmaceutical business to have "own use" clauses in sales contracts precluding resale for profit.

75. Government health care programs, such as Medicare, also treat oncology clinics differently than other purchasers. The amount of reimbursement and the formula utilized by the

government for oncology clinics are different than that which are used for other industry participants, such as hospitals.

76. Most oncology clinics purchase drugs through entities called “specialty distributors.” Specialty distributors deliver oncology drugs, which often require careful handling (*e.g.*, refrigeration), to thousands of oncology clinics. These specialty distributors are licensed to distribute to oncology clinics.

77. Oncology clinics have formed their own Group Purchasing Organizations (“GPO”) to negotiate with drug manufacturers. Historically, certain purchasers of pharmaceuticals have benefited from collectively bargaining with drug manufacturers through GPOs. Hospitals, for instance, belong to GPOs. These hospital GPOs generally do not permit oncology clinics to participate. In recent years, oncology clinics began to form specialized GPOs in an effort to achieve lower prices.

78. The sale of RBCGF drugs to oncology clinics is a market recognized by industry and government.

79. There are high barriers to entry in the sale of RBCGF drugs. Foremost are Amgen’s exclusive patent rights over epoetin alfa. A market entrant would have to commit massive resources to fund clinical research to: (1) demonstrate the safety and effectiveness of a new drug, (2) secure regulatory approval for its distribution in the United States, (3) promote and sell the product, and (4) design around Amgen’s formidable patent estate.

**K. Sales Of WBCGF Drugs To Oncology Clinics Constitute A Distinct And Separate Product Market**

80. The sale of WBCGF drugs in the United States is a relevant product market separate and distinct from the sale of RBCGF drugs.



81. WBCGF drugs are unique products, as they are the only products that alleviate the symptoms associated with treatment-induced neutropenia.

82. The sale of WBCGF drugs to oncology clinics is a market recognized by industry and government.

83. There are high barriers to entry in the sale of WBCGF drugs. There are no potential entrants on the horizon. Any potential competitor to Amgen's WBCGF drug monopoly would face what Amgen claims is a broad patent portfolio. Therefore, to enter these markets, an entrant would have to commit massive resources to fund clinical research to (1) demonstrate the safety and effectiveness of a new drug, (2) and secure regulatory approval for its distribution in the United States and (3) promote and sell the product, and (4) design around Amgen's formidable patent estate.

**L. Amgen Achieved A Monopoly In The Sale Of RBCGF Drugs To Oncology Clinics And Currently Maintains This Monopoly**

84. Amgen achieved a monopoly in the sales of RBCGF drugs to oncology clinics through the unlawful and economically coercive conduct of conditioning the receipt of substantial price rebates on the WBCGF drugs that clinics must purchase from Amgen on the purchase of Amgen's RBCGF drug Aranesp. In October 2005, Amgen's market share of sales of RBCGF drugs to oncology clinics was 66% of the market share. Amgen has since increased and maintained its monopoly share in the RBCGF drug market.

**V. CLASS ACTION ALLEGATIONS**

85. Plaintiff brings this action on behalf of themselves and, pursuant to Rule 23 of the Federal Rules of Civil Procedure, as representatives of a class (the "Class" or "Plaintiff Class") defined as:

All persons and entities in the United States and its territories who paid all or a portion of the cost for Aranesp administered in an oncology clinic during the period April 2004 to the present.

Excluded from the Class are those who make flat co-pays and those whose co-pay was fully reimbursed by an insurer or other third party.

86. The Class is so numerous that joinder of each of the members of the Class would be impracticable. There are thousands of third-party payers who made payments for Aranesp and tens of thousands of consumers who did so as well.

87. There are questions of law and fact which are common to the claims of Plaintiff and the Class, which predominate over questions affecting only individual Class members.

These common questions include, but are not limited to:

- a. Whether Defendants' conduct violated federal and state antitrust laws;
- b. Whether, and to what extent, the conduct of Defendants caused injury to Plaintiff and members of the Class, and, if so, the appropriate measure of damages; and
- c. Whether Plaintiff and members of the Class are entitled to injunctive relief.

88. Plaintiff's claims are typical of the claims of the members of the Class, in that Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

89. Plaintiff will fairly and adequately assert and protect the interests of the Class. Plaintiff's interests coincide with, and are not antagonistic to, the interests of the other members of the Class.

90. Plaintiff's counsel are experienced and competent in the prosecution of complex class action litigation.

91. The questions of law and fact which are common to the claims of Plaintiff and the Class predominate over questions, if any, that may affect only individual members of the Class because, among other reasons, Defendants have acted on grounds generally applicable to the entire Class.

92. This class action would preclude the potential for inconsistent or contradictory individual judgments that would dispose of or impair the interests of other prospective Class members not parties to individual litigation. This class action would establish compatible and consistent standards of conduct for Defendants.

93. Defendants have acted or refused to act on grounds generally applicable to the Class, thereby making final injunctive relief or corresponding declaratory relief appropriate with respect to the Class as a whole.

94. Class action treatment is the superior (if not the only) method for the fair and efficient adjudication of this controversy because, among other reasons, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding by means of class action, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh the difficulties, if any, which may arise in the management of this case as a class action.

## **VI. CAUSES OF ACTION**

### **FIRST CLAIM FOR RELIEF**

#### **(Declaratory And Injunctive Relief Under § 16 Of The Clayton Act)**

95. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

96. Defendants' conduct, as detailed herein, constitute violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. § 1.

97. Defendants and their co-conspirators agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and non-competitive levels, the price of Aranesp and lessened competition in the relevant market.

98. The acts committed by Defendants and their co-conspirators as alleged herein unlawfully restrained interstate and foreign commerce and are against public policy.

99. Plaintiff and the members of the Class were injured by reason of unlawful acts of Defendants and their co-conspirators as alleged herein.

100. Plaintiff and the members of the Class, pursuant to Rule 57 of the Federal Rules of Civil Procedure and 18 U.S.C. § 2201(a), hereby seek a declaratory judgment that Defendants' conduct in seeking to prevent competition as described herein violates Section 2 of the Sherman Act.

101. Plaintiff and the members of the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by Defendants' unlawful conduct, and other relief so as to assure that similar anti-competitive conduct does not occur in the future.

**SECOND CLAIM FOR RELIEF**  
***(Per Se And Rule Of Reason Unlawful Tying In Violation Of***  
**California § 16700 Or, Alternatively, State Antitrust Laws)**

102. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

103. Amgen is a Delaware corporation with its principal place of business in the State of California and is subject to the laws of the State of California.

104. As corporations that maintain their principal place of business in the State of California, Defendants have a reasonable likelihood of being sued with the State of California for the wrongful conduct in which they have engaged.

105. The Cartwright Act, § 16755, provides as follows: “Any violation of this chapter is a conspiracy against trade . . .” Plaintiff is empowered by the Cartwright Act § 16750 to commence a private action for up to three times their damages due to the injuries they have suffered and continue to suffer as a result of Defendants’ violations of the Cartwright Act. The Cartwright Act further states:

Any person who is injured in his or her business or property by reason of anything forbidden or declared unlawful by this chapter, may sue therefore . . . and [is entitled] to recover three times the damages sustained by him or her, [including] interest[.]

Cal. Bus. & Prof. Code § 16750(a).

106. Plaintiff is a “person” within the meaning of the Cartwright Act as defined in § 16702.

107. Defendants acted with specific intent to obtain monopoly power in the relevant market. In addition, Defendants have profited significantly from the aforesaid monopolization and attempted monopolization. Defendants’ monopolistic profits come at the expense and detriment of the Plaintiff and members of the Class.

108. Amgen has engaged in an unlawful contract, combination, conspiracy and agreement in unreasonable restraint of trade and commerce, in violation of California Bus. & Prof. Code § 16700, *et seq.* This includes agreements with oncology clinics that force them to purchase all or nearly all of their demand for RBCGF drugs from Amgen.

109. The product characteristics, uses and character of demand for RBCGF drugs (which are used to treat chemotherapy-induced anemia but not neutropenia) are different from

the product characteristics, uses and the character of demand for WBCGF drugs (products that treat neutropenia, but not anemia). RBCGF and WBCGF drugs are distinct products: they are used to treat different conditions and are not functionally interchangeable.

110. At all times relevant to this action, Amgen has had market power in the sale of WBCGF drugs sufficient to force oncology clinics that purchase WBCGF drugs to also purchase Aranesp regardless of whether these purchasers actually preferred Procrit.

111. A substantial amount of interstate commerce has been and is being affected by Amgen's tying arrangement. The total purchases of RBCGF drugs by oncology clinics was projected to exceed \$2.8 Billion in 2005.

112. Amgen's tying arrangement forces oncology clinics to purchase all or nearly all of their demand for RBCGF drugs from Amgen in a tied package with Amgen's WBCGF drugs. Pursuant to Amgen's pricing schemes, which offer significant rebates for the purchase of Amgen's dominant WBCGF drugs if they are purchased in a package with large quantities of Aranesp, the only economically viable option for oncology clinics that need WBCGF drugs increasingly is for them to purchase all or nearly all of their RBCGF drugs from Amgen.

113. Amgen's tying arrangement has substantially foreclosed and will continue to substantially foreclose Ortho from competing with Amgen for the sale of RBCGF drugs to oncology clinics based on the efficacy of its product and the price of its product on a stand-alone basis.

114. Amgen's tying arrangement has no legitimate business purpose. It achieves no legitimate efficiency benefits and has the anticompetitive effect of foreclosing competition on the merits for the sale of RBCGF drugs to oncology clinics.

115. Amgen's tying arrangement has adversely affected competition in the sale of RBCGF drugs to oncology clinics and has increased the cost to consumers in this market and will continue to do so unless enjoined.

116. Amgen's restraint of trade has been effectuated by a variety of unlawful conduct undertaken with the purpose and effect of eliminating competition in the sale of RBCGF drugs, including but not limited to:

- Conditioning the sale of RBCGF drugs on the purchase of WBCGF drugs;
- Granting rebates on the sale of WBCGF drugs conditioned upon the purchase of RBCGF drugs from Amgen;
- Granting multi-product rebates conditioned upon meeting disguised market share requirements for RBCGF and WBCGF drugs; and
- Entering into agreements that have the purpose and effect of requiring customers to purchase all or almost all of their requirements for RBCGF drugs from Defendants.

117. Amgen's exclusionary practices have caused and will continue to cause substantial anticompetitive effects on the sale of RBCGF drugs to Plaintiff. Amgen's conduct has substantially foreclosed and will continue to substantially foreclose competition from Ortho in the sale of RBCGF drugs to Plaintiff. Amgen's conduct has raised and will continue to raise barriers to entry for potential competitors for the sale of RBCGF and WBCGF drugs.

118. Amgen's practices have no legitimate business justification and pose no pro-competitive benefit, and Plaintiff paid higher prices for RBCGF drugs as a result.

**THIRD CLAIM FOR RELIEF**  
**(Violation Of California's Unfair Competition Law,**  
**Business And Professional Code § 17200, *Et Seq.*)**

119. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

120. Defendants' actions constitute unfair and deceptive unlawful practices committed in violation of the Unfair Competition Law, Bus. & Prof. Code §§ 17200, *et seq.*

121. Defendants violated the "fraudulent," "unfair" and "unlawful" prongs of § 17200 by engaging in the conduct described above that is subject to revision upon the completion of discovery.

122. Defendants are licensed to do business in the State of California and California is Defendants' principal place of business. As such, Defendants maintain a reasonable expectation of being sued in California under California's laws for their illegal conduct.

123. As a direct and proximate result of Defendants' conduct, Plaintiff and the Class members have been injured in an amount to be proven at trial.

**FOURTH CLAIM FOR RELIEF**  
**(Violation Of State Antitrust Laws)**

124. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

125. To the extent the Court rules that California's antitrust law does not apply nationwide, Plaintiff alleges that:

- a. Defendants' aforementioned practices violated Alabama Code § 6-5-60, *et seq.*;
- b. Defendants' aforementioned practices violated Alaska Stat. 45.50.580(a) & (b);
- c. Defendants aforementioned practices violated Arizona Revised Stat. Code §§ 44-1401 *et seq.*
- d. Defendants aforementioned practices violated District of Columbia Code Ann. §§ 28-4503 *et seq.*



e. Defendants' aforementioned practices violated the Florida Antitrust Act, Fla. Stat. Ann. §§ 542.15, *et seq.*;

f. In this complaint, Plaintiff does not allege a violation of Hawaii Rev. Stat. 480-1 *et seq.*, but seeks to comply with the procedural prerequisites in Haw. Rev. Stat. 480-13.3, to file and maintain a private indirect-purchaser class action.

g. Defendants' aforementioned practices violated Iowa Code §§ 553.1 *et seq.*

h. Defendants' aforementioned practices violated Kansas Stat. Ann. §§ 50-101 *et seq.*

i. Defendants' aforementioned practices violated the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. §§ 367.110, *et seq.*;

j. Defendants' aforementioned practices violated the Louisiana Monopolies Law, La. Rev. Stat. Ann. §§ 51-121, *et seq.*;

k. Defendants' aforementioned practices violated 10 Maine Rev. Stat. §§ 1101 *et seq.*

1. Defendants' aforementioned practices violated the Massachusetts Antitrust Act, Mass. Gen. Laws, ch. 93;

m. Defendants' aforementioned practices violated Michigan Comp. Laws. Ann. §§ 445.773 *et seq.*

n. Defendants' aforementioned practices violated Minnesota Stat. §§ 325D.52 *et seq.*

o. Defendants' aforementioned practices violated Mississippi Code Ann. § 75-21-1 *et seq.*

p. Defendants' aforementioned practices violated Nebraska Rev. Stat. §§ 59-801 *et seq.*

q. Defendants' aforementioned practices violated Nevada Rev. Stat. Ann. §§ 598A *et seq.*

r. Defendants' aforementioned practices violated the New Jersey Antitrust Act, N.J. Stat. Ann. §§ 56:9-1, *et seq.*;

s. Defendants' aforementioned practices violated New Mexico Stat. Ann. §§ 57-1-1 *et seq.*

t. Defendants' aforementioned practices violated New York Gen. Bus. Law § 340 *et seq.*

u. Defendants' aforementioned practices violated North Carolina Gen. Stat. §§ 75-1 *et seq.*

v. Defendants' aforementioned practices violated North Dakota Cent. Code §§ 51-08.1-01 *et seq.*

w. Defendants' aforementioned practices violated South Dakota Codified Laws Ann. §§ 37-1 *et seq.*

x. Defendants' aforementioned practices violated Tennessee Code Ann. §§ 47-25-101 *et seq.*

y. Defendants' aforementioned practices violated Vermont Stat. Ann. 9 §§ 2453 *et seq.*

z. Defendants' aforementioned practices violated West Virginia Code §§ 47-18-1 *et seq.*

aa. Defendants' aforementioned practices violated Wisconsin Stat. §§ 133.01 *et seq.*

126. As a direct and proximate result of Defendants' unlawful conduct, Class members in each of these States have been injured in their businesses and property in that they paid more for the drugs at issue than they would have paid absent Defendants' unlawful conduct.

## VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. That the Court declare, adjudge and decree that Amgen has committed the violations of law alleged herein;

B. That the Court award to Plaintiff the damages sustained as a result of the illegal conduct of Amgen, in an amount to be proved at trial, to be trebled according to law, plus interest (including prejudgment interest), attorneys' fees and costs of suit, and such other and further relief as this Court may deem just and proper.

DATED: November 2, 2007

SHEET METAL WORKERS NATIONAL  
HEALTH FUND

By: s/ David J. Cohen  
David J. Cohen  
**SALTZ MONGELUZZI BARRETT & BENDESKY, P.C.**  
One Liberty Place, 52nd Floor  
Philadelphia, PA 19103  
(215) 496-8282  
(215) 496-0999 (fax)

Steve W. Berman  
**HAGENS BERMAN SOBOL SHAPIRO LLP**  
1301 Fifth Avenue, Suite 2900  
Seattle, WA 98101  
(206) 623-7292  
(206) 623-0594 (fax)

Elizabeth A. Fegan  
Timothy P. Mahoney  
Daniel J. Kurowski  
**HAGENS BERMAN SOBOL SHAPIRO LLP**  
820 North Blvd, Suite B  
Oak Park, Illinois 60301  
(708) 776-5600  
(708) 776-5601 (fax)

Kenneth A. Wexler  
Jennifer Fountain Connolly  
**WEXLER TORISEVA WALLACE LLP**  
55 W. Monroe, Suite 3300  
Chicago, IL 60603  
(312) 346-2222  
(312) 346-0022 (fax)

James G. Stranch  
R. Jan Jennings  
**BRANSTETTER, STRANCH & JENNINGS PLLC**  
227 Second Avenue North  
Fourth Floor  
Nashville, TN 37201-1631  
(615) 254-8801  
(615) 250-3937 (fax)

*Attorneys for Plaintiff and the Proposed Class*

### DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

DATED: November 2, 2007

By: \_\_\_\_\_ s/ David J. Cohen  
David J. Cohen  
**SALTZ MONGELUZZI BARRETT & BENDESKY, P.C.**  
One Liberty Place, 52nd Floor  
Philadelphia, PA 19103  
(215) 496-8282  
(215) 496-0999 (fax)

*Attorneys for Plaintiff and the Proposed Class*

# EXHIBIT G

The New York Times  
nytimes.com

BRENDAN  
GLEESON

May 9, 2007

## Doctors Reap Millions for Anemia Drugs

By [ALEX BERENSON](#) and [ANDREW POLLACK](#)

Two of the world's largest drug companies are paying hundreds of millions of dollars to doctors every year in return for giving their patients [anemia](#) medicines, which regulators now say may be unsafe at commonly used doses.

The payments are legal, but very few people outside of the doctors who receive them are aware of their size. Critics, including prominent [cancer](#) and kidney doctors, say the payments give physicians an incentive to prescribe the medicines at levels that might increase patients' risks of heart attacks or strokes.

Industry analysts estimate that such payments — to cancer doctors and the other big users of the drugs, kidney dialysis centers — total hundreds of millions of dollars a year and are an important source of profit for doctors and the centers. The payments have risen over the last several years, as the makers of the drugs, [Amgen](#) and [Johnson & Johnson](#), compete for market share and try to expand the overall business.

Neither Amgen nor Johnson & Johnson has disclosed the total amount of the payments. But documents given to The New York Times show that at just one practice in the Pacific Northwest, a group of six cancer doctors received \$2.7 million from Amgen for prescribing \$9 million worth of its drugs last year.

Yesterday, the [Food and Drug Administration](#) added to concerns about the drugs, releasing a report that suggested that their use might need to be curtailed in cancer patients. The report, prepared by F.D.A. staff scientists, said no evidence indicated that the medicines either improved quality of life in patients or extended their survival, while several studies suggested that the drugs can shorten patients' lives when used at high doses. Yesterday's report followed the F.D.A.'s decision in March to strengthen warnings on the drugs' labels.

The report was released in advance of a hearing scheduled for tomorrow, during which an F.D.A. advisory panel will consider whether the drugs are overused.

The medicines — Aranesp and Epogen, from Amgen; and Procrit, from Johnson & Johnson — are among the world's top-selling drugs, with combined sales of \$10 billion last year. In this country, they represent the single biggest drug expense for Medicare and are given to about a million patients each year to treat anemia caused by kidney disease or cancer [chemotherapy](#).

Dr. Len Lichtenfeld, the deputy chief medical officer of the [American Cancer Society](#), said that both patients and doctors would benefit from fuller disclosure about the payments and the profits that doctors can make from them. "I suspect that Medicare is going to take a very careful look at what is going on here," he said.

Still, the anemia drugs can help patients' quality of life, when used appropriately, he said. "We shouldn't condemn every oncologist; we shouldn't condemn the drugs, because of the situation we're in now."

Federal laws bar drug companies from paying doctors to prescribe medicines that are given in pill form and purchased by patients from pharmacies. But companies can rebate part of the price that doctors pay for drugs, like the anemia medicines, which they dispense in their offices as part of treatment. The anemia drugs are injected or given intravenously in physicians' offices or dialysis centers. Doctors receive the rebates after they buy the drugs from the companies. But they also receive reimbursement from Medicare or private insurers for the drugs, often at a markup over the doctors' purchase price.

Medicare has changed its payment structure since 2003 to reduce the markup, but private insurers still often pay more. Combined with those insurance reimbursements, the rebates enable many doctors to profit substantially on the medicines they buy and then give to patients.

The rebates are related to the amount of drugs that doctors buy, and physicians that agree to use one company's drugs exclusively typically receive higher rebates.

Johnson & Johnson said yesterday in a statement that its rebates were not intended to induce doctors to use more medicine. Instead, the rebates "reflect intense competition" in the market for the drugs, the company said.

Amgen said that rebates were a normal commercial practice and that it had always properly promoted its drugs.

"Amgen is dedicated to patient safety," said David Polk, a spokesman. "We believe our contracts support appropriate anemia management and our product promotion is always strictly within the label."

Both companies' stocks fell yesterday after release of the F.D.A. report. Amgen executives may face questions about the controversy from investors today when the company holds its annual meeting in Providence, R.I.

Since 1991, when the first of the drugs was still relatively new, the average dose given to dialysis patients in this country has nearly tripled. About 50 percent of dialysis patients now receive enough of the drugs to raise their red blood cell counts above the level considered risky by the F.D.A.

American patients receive far more of the anemia drugs than patients elsewhere, with dialysis patients in this country getting doses more than twice as high as their counterparts in Europe. Cancer care shows a similar pattern. American cancer patients are about three times as likely as those in Europe to get the drugs, and they receive somewhat higher doses.

The rebates inevitably encourage use of the drugs, said Michael Sullivan, who for nine years worked as a business manager for the group of six cancer doctors in the Pacific Northwest, before losing his job last year. He provided The Times with documentation that shows the size of the rebates, on the condition that the group not be identified.

"Personally, I think rebates should go away," said Mr. Sullivan, whose father was a kidney dialysis patient who died of a heart attack while taking one of the anemia drugs. "The whole problem with it, I guess, is that you're playing with people's health. It's not the same as buying widgets."



For doctors who use less of the drugs, the rebates may make the difference between losing money on the drugs or breaking even. Mr. Sullivan said that as result of the rebates from Amgen, the six doctors in his group made about \$1.8 million in net profit on the drugs they prescribed.

Unlike most drugs, the anemia medicines do not come in fixed doses. Therefore, doctors have great flexibility to increase dosing — and profits. Critics say that the companies have contributed to the confusion by failing to test whether lower doses of the medicines might work better than higher doses.

“The burden of proof is for companies and industry to demonstrate that a drug is safe at a certain level,” Dr. Ajay Singh, an associate professor at Harvard Medical School. Dr. Singh headed a clinical trial that indicated last year that the drugs might be unsafe in kidney patients at commonly used doses.

Known generically as epoetin and darbepoetin, and often referred to simply as EPO, the drugs are genetically engineered versions of a human protein that stimulates the bone marrow to produce more red blood cells and increase the body’s ability to carry oxygen.

Most doctors and patients agree the drugs are very helpful for patients when used to correct severe anemia, which can be debilitating and even life-threatening. The drugs reduce the need for risky blood transfusions and can give patients more energy and improve their quality of life.

“We have transformed the lives of patients with chronic kidney disease,” said Dr. Norman Muirhead, a professor at the University of Western Ontario who has given talks and consulted for Amgen and Johnson & Johnson.

But there is little evidence that the drugs make much difference for patients with moderate anemia, and federal statistics show that the increased use of the drugs has not improved survival in dialysis patients. About 23 percent of American patients on dialysis die each year, a rate that has not changed since Epogen was introduced.

Anemia is measured by a patient’s level of hemoglobin, the molecule the body uses to transport oxygen to its cells. Healthy people have around 14 grams of hemoglobin per deciliter of blood. Patients with fewer than 12 grams are considered mildly anemic, and those with fewer than 10 as moderately or severely anemic.

The labels on the drugs, as currently approved by the F.D.A., encourage doctors to aim for a hemoglobin level of 10 to 12. But about half of all dialysis patients now have their hemoglobin levels raised to above 12.

Critics of the drugs say their increased use has been driven by profit. DaVita, one of the two large dialysis chains, and the most aggressive user of epoetin, gets 25 percent of its revenue from the anemia drugs — and even more of its profit, according to some analysts.

Dr. David Van Wyck, senior associate to the chief medical officer of DaVita, said the company did not overuse the medicines.

Doctors determine how much to use, Dr. Van Wyck said. “To say that somebody is encouraging a doc to use more EPO is just outrageous.”

Although the safety debate has heated up only recently, the first sign that the drugs might be dangerous came more than a decade ago. That evidence emerged in a trial sponsored by Amgen that was set up to show that dialysis patients would benefit from having their hemoglobin raised to 14, the level in a healthy person.

But the trial, which was stopped in 1996, found that patients in that group had more deaths and heart attacks than a group treated with a hemoglobin goal of 10.

That trial should have discouraged doctors from using too much epoetin and encouraged Amgen to study the risks further, said Dr. Steven Fishbane, a nephrologist at Winthrop-University Hospital on Long Island.

Instead, use of epoetin continued to soar. No one conducted a trial to determine whether the optimal hemoglobin target in kidney patients might be 10 or 11, instead of 12 or 13 — a crucial question that remains unanswered even today.

Dr. Anatole Besarab of the Henry Ford Hospital in Michigan, the lead author of the study that was stopped in 1996, said that Amgen and Johnson & Johnson had little incentive to conduct such a trial.

Dr. Robert M. Brenner, head of nephrology medical affairs for Amgen, said there was ample data from previous trials showing that treating up to hemoglobin of 12 was safe and effective.

Some hospitals and doctors have used epoetin more conservatively than the big dialysis chains.

Dr. Ronald A. Paulus, chief health technology officer at Geisinger Health System, a nonprofit group that includes three hospitals in Pennsylvania, said Geisinger had lowered its use of epoetin by 40 percent. Its doctors did so simply by monitoring patients more closely and giving them more iron, without which the body cannot make hemoglobin.

Dr. N. D. Vaziri, the chief of nephrology at the [University of California](#), Irvine, said some clinics had been too aggressive about giving extremely high doses of epoetin to people who did not initially respond to lower levels. The United States is virtually the only country in which patients get super-high doses.

“You create a toxicity situation,” said Dr. Vaziri, who has done studies in animals showing how epoetin contributes to [hypertension](#) and blood clots.

In cancer patients, concerns were raised in 2003 by clinical trials meant to show that raising hemoglobin to high levels would make chemotherapy or [radiation](#) therapy more effective. Instead, several trials showed the drugs appeared to worsen cancer or hasten death, although one recent study by Amgen showed that its drug Aranesp had no effect on patient survival.

The conflicting studies are among the issues the F.D.A. advisory committee is expected to discuss tomorrow. Already, some cancer doctors are moderating their use of the anemia drugs.

Dr. Peter Eisenberg, an oncologist in Marin County, Calif., said many doctors had been induced to use more epoetin by the financial incentives and the belief that the drug was helpful.

“The deal was so good,” he said. “The indication was so clear and the downside was so small that docs just worked it into their practice easily.”

“Now it’s much scarier than that,” he said. “We could really be doing harm.”

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FOLEY & LARDNER LLP

ATTORNEYS AT LAW

90 PARK AVENUE  
NEW YORK, NY 10016-1314  
212.682.7474 TEL  
212.687.2329 FAX  
WWW.FOLEY.COM

WRITER'S DIRECT LINE  
212.338.3545  
rkramer@foley.com EMAIL

CLIENT/MATTER NUMBER  
103443-0104

August 1, 2014

All Counsel on the Attached Service List

Re: U.S. ex rel. Hanks v. Amgen, Inc., No. 08-3096-SJ-RML

Dear Counsel,

Attached please find the following documents in support of the motion to dismiss the Fifth Amended Complaint in the above action by defendants Florida Cancer Specialists, P.L. (sued herein as Florida Cancer Specialists & Research Institute); Ayub, Sokol, Matzkowitz and Sennabaum, M.D.s, P.A. d/b/a New Hope Cancer Center; Coastal Oncology, P.L.; J. Paonessa, M.D., P.A. (sued herein as Gulfcoast Oncology Associates); and Pasco Hernando Oncology Associates, P.A.:

- Notice of Motion;
- Memorandum of Law in Support; and
- Declaration of Rachel Kramer with Exhibits.

Very truly yours,

*s/Rachel E. Kramer*

Rachel E. Kramer

Attachments

cc: Hon. Sterling Johnson, Jr., U.S.D.J. (via ECF without enclosures)  
Hon. Robert M. Levy, U.S.M.J. (via ECF without enclosures)

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SILICON VALLEY

TALLAHASSEE  
TAMPA  
TOKYO  
WASHINGTON, D.C.

## SERVICE LIST

### ***Via E-mail and U.S. Mail:***

Deborah B. Zwany  
United States Attorney's Office  
Eastern District of New York  
271 Cadman Plaza East  
Brooklyn, NY 11201-1820  
E-mail: Deborah.Zwany@usdoj.gov

Mark D. Shifton  
Seiger Gfeller Laurie LLP  
100 Overlook Center  
Second Floor  
Princeton, NJ 08540  
E-mail: mshifton@sgllawgroup.com

M. Darren Traub  
Akerman LLP  
666 Fifth Avenue, 20th Floor  
New York, NY 10103  
E-mail: Darren.traub@akerman.com

Cindy A. Laquidara  
Akerman LLP  
50 North Laura Street, Suite 3100  
Jacksonville, FL 32202-3646  
E-mail: cindy.laquidara@akerman.com

### ***Via E-mail Only:***

Hays Gorey  
GeyerGorey LLP  
1776 I Street, NW  
Washington, DC 20006  
E-mail: hays.gorey@geyergorey.com

Robert Hennig  
The Law Offices of Rob Hennig  
1875 Century Park East, Suite 1770  
Los Angeles, CA 90067  
E-mail: rob@robhennig.com

Carl H. Jr. Loewenson, Jr.  
Joseph Alexander Lawrence  
Morrison & Foerster LLP  
250 West 55th Street  
New York, NY 10019  
E-mail: cloewenson@mofo.com  
E-mail: alawrence@mofo.com

Ryan Hassanein  
Nicholas S. Napolitan  
Morrison & Foerster LLP  
425 Market Street  
San Francisco, CA 94105  
E-mail: nnapolitan@mofo.com  
E-mail: rhassanein@mofo.com

Daniel Stabile  
Joseph M. Goldstein  
Shutts & Bowen  
201 S. Biscayne Blvd.  
Miami, FL 33131  
E-mail: dstabile@shutts.com  
E-mail: jgoldstein@shutts.com

Adam P. Schwartz  
Stefanie Lincoln  
Carlton Fields, P.A.  
4221 W. Boy Scout Blvd  
Suite 1000  
Tampa, FL 33607  
E-mail: aschwartz@carltonfields.com  
E-mail: slincoln@cfjblaw.com

Natalie Napierala  
Carlton Fields, P.A.  
405 Lexington Avenue, 29th Fl  
New York, NY 10174  
E-mail: nnapierala@carltonfields.com

Jeremy P. Burnette  
Kilpatrick Townsend Stockton LLP  
1100 Peachtree Street, Suite 2800  
Atlanta, GA 30309  
E-mail: JBurnette@kilpatricktownsend.com

James W. Boswell  
Michael E. Paulhus  
King & Spalding  
1180 Peachtree Street  
Atlanta, GA 30309  
E-mail: jboswell@kslaw.com  
E-mail: mpaulhus@kslaw.com

Wendy H. Waszmer  
King & Spalding  
1185 Avenue of the Americas  
34th Floor  
New York, NY 10036  
E-mail: wwaszmer@kslaw.com

Anthony Cochran  
John D. Dalbey  
Chilivis, Cochran, Larkins & Bever, LLP  
3127 Maple Dr. NE  
Atlanta, GA 30305  
E-mail: alc@cclblaw.com  
E-mail: jddalbey@cclblaw.com

Joseph R. Odachowski  
Taylor Odachowski Schmidt & Crossland  
LLC  
300 Oak Street, Suite 200  
Saint Simons Island, GA 31522  
E-mail: jodachowski@tosclaw.com

Elise Margaret Gabriel  
K&L Gates  
599 Lexington Avenue  
New York, NY 10022  
E-mail: elise.gabriel@klgates.com

Armando Llorens  
Furgang & Adwar, L.L.P.  
1325 Avenue of the Americas, 28th Floor  
New York, New York 10019  
E-mail: Armando@furgang.com